# Extracorporeal Shock Wave Therapy for the Treatment of Chronic Calcifying Tendonitis of the Rotator Cuff

## A Randomized Controlled Trial

Ludger Gerdesmeyer, MD
Stefan Wagenpfeil, PhD
Michael Haake, MD, PhD
Markus Maier, MD
Markus Loew, MD
Klaus Wörtler, MD
Renee Lampe, MD
Romain Seil, MD
Gerhart Handle, MD
Susanne Gassel, MD
Jan D. Rompe, MD

**Context** Extracorporeal shock wave therapy (ESWT) has been used to treat calcific tendonitis of the shoulder, but trials of ESWT for this purpose have had methodological deficiencies and thus there is limited evidence for its effectiveness.

**Objective** To determine whether fluoroscopy-guided ESWT improves function, reduces pain, and diminishes the size of calcific deposits in patients with chronic calcific tendonitis of the shoulder.

**Design, Setting, and Participants** Double-blind, randomized, placebo-controlled trial conducted between February 1997 and March 2001 among 144 patients (of 164 screened) recruited from referring primary care physicians, orthopedic surgeons, and sports physicians in 7 orthopedic departments in Germany and Austria.

**Interventions** Either high-energy ESWT, low-energy ESWT, or placebo (sham treatment). The 2 ESWT groups received the same cumulative energy dose. Patients in all 3 groups received 2 treatment sessions approximately 2 weeks apart, followed by physical therapy.

**Main Outcome Measures** The primary end point was the change in the mean Constant and Murley Scale (CMS) score from baseline to 6 months after the intervention. Secondary end points were changes in the mean CMS scores at 3 and 12 months, as well as changes in self-rated pain and radiographic change in size of calcific deposits at 3, 6, and 12 months.

**Results** Of 144 patients enrolled, all completed treatment as randomized and 134 completed the 6-month follow-up. Both high-energy and low-energy ESWT resulted in significant improvement in the 6-month mean (95% confidence interval [CI]) CMS score compared with sham treatment (high-energy ESWT: 31.0 [26.7-35.3] points; low-energy ESWT: 15.0 [10.2-19.8] points; sham treatment: 6.6 [1.4-11.8] points; $P<.001$ for both comparisons). Patients who received high-energy ESWT also had significant 6-month CMS improvements compared with those who received low-energy ESWT ($P<.001$). We found similar results for both the 3-month and 12-month CMS comparisons, as well as for self-rated pain and radiographic changes at 3, 6, and 12 months.

**Conclusions** Both high-energy and low-energy ESWT appeared to provide a beneficial effect on shoulder function, as well as on self-rated pain and diminished size of calcifications, compared with placebo. Furthermore, high-energy ESWT appeared to be superior to low-energy ESWT.

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CALCIFIC TENDONITIS OF THE rotator cuff is a well-known source of shoulder pain.[1] Estimates of the overall incidence vary widely, ranging between 2.5% and 20%,[1-3] depending on both clinical criteria and radiographic technique. The disease is usually self-limiting but the natural course is variable.[1-5] For instance, Gärtner[6] reported that calcifications with sharp margins and homogeneous or nonhomogeneous structure disappeared spontaneously in 33% of patients over a period of 3 years, but that 85% of fluffy accumulations did so during the same time period. In 1941, Bosworth[1] reported that 6.4% of calcific lesions showed spontaneous resorption.

Clinically, it is important to distinguish calcific tendonitis from a rotator cuff tear as a source of shoulder pain.[7] Several authors have found no correlation between the presence of a tendon tear and calcific tendonitis.[4,7-10] The treatment of patients with calcific tendonitis typically is conservative, including use of subacromial cortisone injections, physical therapy,

**Author Affiliations** are listed at the end of this article.
**Corresponding Author and Reprints:** Ludger Gerdesmeyer, MD, Department of Orthopedic Surgery and Sportstraumatology, Technical University Munich, Ismaninger Strasse 22, D-81675 Munich, Germany (e-mail: Gerdesmeyer@aol.com).

and systemic nonsteroidal anti-inflammatory drugs, although evidence of efficacy is limited.[11,12] For patients with chronic calcification, surgical removal of the deposits, either with an open procedure or endoscopically, has been reported to relieve symptoms.[13-19]

Ultrasound treatment may be an alternative to surgery. Ebenbichler et al[20] reported that ultrasonic energy accelerated functional improvement in patients with acute calcific tendonitis, although efficacy was no better than that achieved with placebo in long-term follow-up. Although extracorporeal shock wave therapy (ESWT) has demonstrated encouraging results in the treatment of calcified deposits,[21-25] all of these trials have had methodological deficiencies.[12] We compared the effectiveness of high-energy and low-energy ESWT vs placebo (ie, sham treatment) in patients with chronic, symptomatic calcific tendonitis of the supraspinatus tendon.

## METHODS

### Patients

Our study was a randomized, placebo-controlled trial in 7 sites in Germany and Austria and was conducted between February 1997 and March 2001. Participants were assigned to receive either high-energy ESWT, low-energy ESWT, or sham treatment (FIGURE). In designing the trial we adhered to the standardized guidelines of good clinical practice from the International Conference on Harmonization.[26,27] All patients provided written informed consent. The trial was approved by the ethics committee of the Faculty of Medicine of the Technical University of Munich.

Potential participants were made aware of the trial by reports in the press, by health insurance companies, or by orthopedic practitioners or hospitals. They were referred to one of the participating centers in Germany and Austria. To be eligible for the trial, participants had to have a history of at least 6 months of pain or tenderness from idiopathic calcific tendonitis, type I or II according to Gärtner,[6] that was resistant to conservative treatment.

Participants were eligible if they were aged 18 years or older, had calcific deposits of 5 mm in diameter or larger on radiography, and had had symptoms for at least 6 months. Rotator cuff tears and subacromial bursitis were ruled out in all patients by clinical and sonographic examination, and when in doubt, by magnetic resonance imaging prior to randomization and at all follow-up visits. Participants with type III Gärtner deposits were excluded because of high probability of spontaneous resolution.[6] We required that all participants had had previous conservative treatments, including both physiotherapy (eg, active and passive exercise, mobilization, manual therapy and massage, muscle strengthening) and local anesthetic or corticosteroid injections. We also verified that all participants had tried nonsteroidal anti-inflammatory drugs such as ibuprofen or diclofenac. Exclusion criteria included rheumatic disease, connective tissue disease, or diabetes; coagulation disturbance; pregnancy; glenohumeral or acromioclavicular joint arthritis; previous surgery for shoulder pain; bursitis, infection, or tumor of the shoulder; instability of the shoulder or rotator cuff tear; type III calcific deposit (by Gärtner classification); abnormal peripheral neurologic findings; and unsuccessful prior ESWT.

### Interventions

Treatment allocation was determined immediately before the first treatment by block randomization (48 per block) using a computer-generated algorithm at a central location. Assignments were then delivered by telephone and kept in sealed opaque envelopes. Patients, as well as the follow-up evaluators, were blinded to treatment assignments.

Patients were assigned to receive either high-energy ESWT, low-energy ESWT, or sham treatment. All patients had had at least a 1-month, therapy-free period before the first treatment with ESWT. Patients in all groups were informed that sometimes the procedure could be painful and could take up to 1 hour per session due to the necessity to control and refocus the shock waves exactly.

Immediately after randomization, the patient was placed in the prone position. Using fluoroscopy in an anterior-posterior view, the shoulder was rotated until the calcific deposit was identified in a free position. For the high-energy and low-energy groups, a shock wave head was coupled to the shoulder with a thin sheet of polyethylene foil placed between the shock wave head and the patient. Coupling gel was used between the shock wave head and the foil and between the foil and shoulder.

The exact focus position was controlled using fluoroscopy during the ESWT procedure and adjusted if necessary. After the energy level was increased up to the assigned treatment level, the assigned number of shock waves were applied. Patients in the high-energy group received 1500 shock waves of 0.32 mJ/mm$^2$ per treatment, while those in the low-energy group received 6000 shock waves of 0.08 mJ/mm$^2$. In both groups, 120 impulses were applied per minute. Adequate intravenous analgesia and sedation were provided as necessary. Local anesthetics were prohibited. All patients received a second ESWT treatment at 12 to 16 days; thus, patients in each group received a cumulative energy dose of 0.960 J/mm$^2$. Each treatment session lasted as long as 1 hour. Measurements with glass-fiber hydrophones in accordance with International Electrotechnical Commission (IEC) procedures[28] demonstrated that shock waves were unaffected by the polyethylene foil when used with ultrasound coupling gel on both sides of the foil (data not shown).

In the sham treatment, an air-chambered polyethylene foil with coupling gel was placed against the patient's skin, but no coupling gel was applied to the site of the shock wave head. The air-chambered polyethylene foil was placed between the patient and the water cushion of the ESWT device in the same technique as in the other 2

groups. In every other respect the setup was the same. Measurements with glass-fiber hydrophones in accordance with IEC procedures demonstrated that no shock waves could pass through the foil. Patients in the sham treatment group received 1500 shock waves per treatment with 120 impulses per minute after the energy level reached the assigned treatment level of 0.32 mJ/mm$^2$ (although a total of 0.960 J/mm$^2$ was emitted from the ESWT device over the 2 treatments). The patients' prone position prevented them from seeing the device, but they could hear the typical sound of shock waves being generated.

Patients in all 3 groups underwent 10 physiotherapy sessions after the intervention. This included active and passive exercise mobilization techniques, massage, and manual therapy to prevent worsening in range-of-motion, muscular deficit, or imbalance.

Rescue medication was allowed throughout the entire study if pain became unbearable (2 g of paracetamol or 2 g of acetaminophen per day for up to 14 days following the last treatment; thereafter, 2 g of paracetamol or 2 g of acetaminophen per week). No other therapies (eg, chiropractic, laser, acupuncture, ultrasound, other nonsteroidal anti-inflammatory drugs, or corticosteroids) were allowed until after the 6-month follow-up.

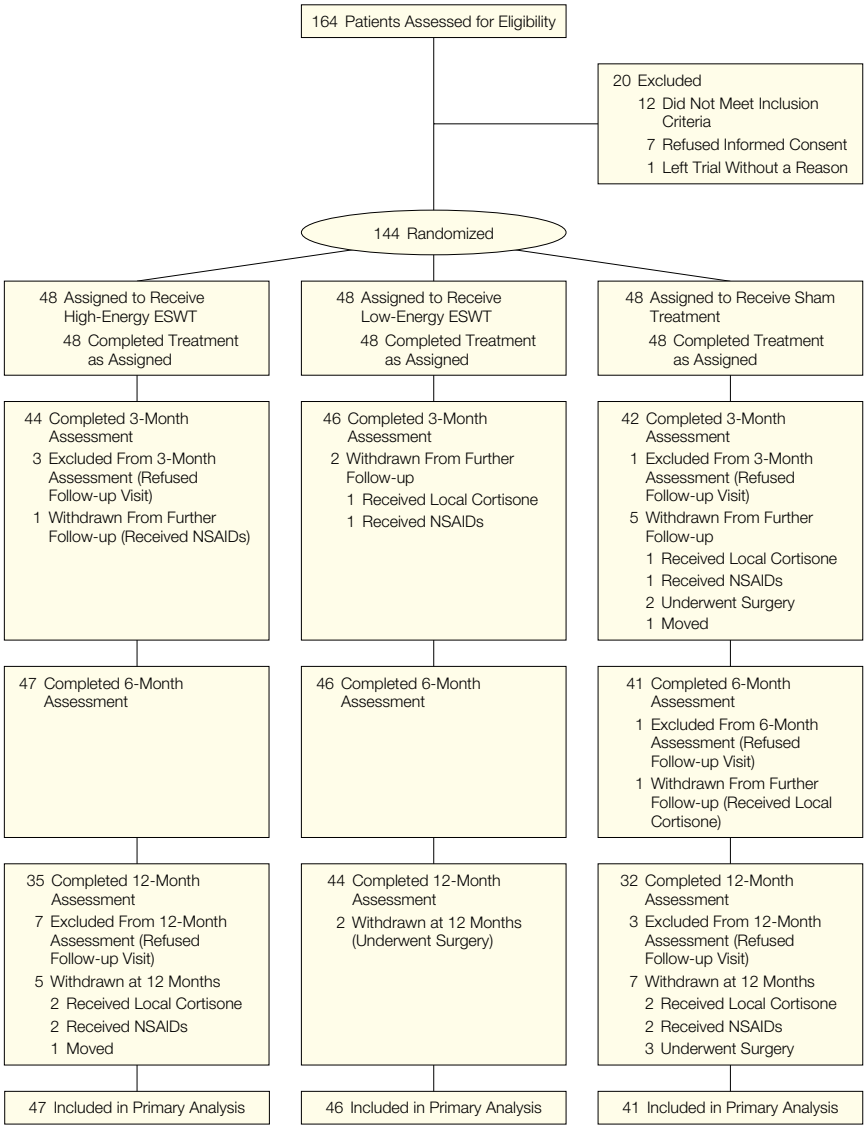
## Outcome Measures

The primary end point was the change in the mean Constant and Murley Scale (CMS)[29] score from baseline to 6 months after treatment. Comparisons between the sham treatment group and the other 2 groups were prespecified, while comparisons between the groups receiving high-energy and low-energy ESWT were performed in a post hoc fashion.

The CMS is a standardized simple clinical method of assessing shoulder function and has a maximum score of 100 points, with both subjective (35 points) and objective (65 points) components. The CMS has been reported to have high interobserver and intraobserver reliability.[30] The subjective parameters assess the degree of pain perception (15 points) and the ability to perform the normal tasks of daily living in both activity- and position-related terms (20 points). The objective parameters include testing of active range of motion (40 points) and shoulder power (25 points). All observers who assessed the CMS were blinded. All were experienced and used a goniometer to evaluate the active forward and lateral elevation and body landmarks reached by the patient to assess the internal/external rotation. The power in abduction was measured using a spring balance.

The 6-month interval was selected because we expected that healing would likely be evident (although not necessarily complete) at this point. Clinically relevant improvement was defined as a 30% increase from baseline on the CMS score. Patients who needed additional therapies, except the allowed amount of rescue medication and physiotherapy, were defined as failing treatment.

**Figure.** Flow of Participants Through the Trial




ESWT indicates extracorporeal shock wave therapy; NSAIDs, nonsteroidal anti-inflammatory drugs.

Secondary end points were changes in mean 3- and 12-month CMS scores, as well as in self-rated pain at 3, 6, and 12 months as assessed by a visual analog scale (VAS) (0 points = no pain; 10 points = unbearable pain). We also assessed the presence and size of calcified deposits at 3, 6, and 12 months by conventional radiography. The technique was standardized in terms of position of the shoulder and arm, distance from the radiographic film, and exposure.[31] The localization of calcifications within a specific tendon was determined by anteroposterior radiographs of the shoulder obtained in 45° external and 45° internal rotation.[31] These 2 standard anterior-posterior views were obtained within 14 days before intervention to exclude spontaneous healing before treatment and again at 3, 6, and 12 months after treatment and analyzed by an independent skeletal radiologist with no knowledge of the type of treatment used. Success was defined as complete disappearance of the deposit.

### Statistical Analysis

Changes in CMS scores for pain, activities of daily living, range of motion, and power, as well changes in VAS pain scores and size of calcific deposit were defined as the difference between the 3-month, 6-month, and 12-month measurements and respective baseline values. These absolute changes were the variables of interest and analysis.

All analyses were performed with SPSS release 11.5 (SPSS Inc, Chicago, Ill). Computed *P* values were 2-sided, and $P<.05$ was used to determine statistical significance. For group comparisons of changes we used the *t* test for independent samples or the Welch test, as appropriate. Significance levels for multiple comparisons were adjusted with the Bonferroni-Holm procedure. All analyses of the primary outcome were performed according to the principle of intention-to-treat, with missing values imputed with last observation carried forward. For the secondary end points, descriptive statistics and 95% confidence intervals were calculated.

We computed that a sample of 144 patients had 90% power to find a 15% difference in the primary outcome, as compared with sham treatment, given an $\alpha$ level of .025. We tested for selection bias according to the method of Berger and Exner.[32] To examine for treatment-center effects we applied the Kruskal-Wallis test on the primary outcome variable within each of the treatment groups separately and an analysis of covariance with treatment-center interaction.

**Table 1.** Baseline Characteristics

| Characteristic | High-Energy ESWT (n = 48) | Low-Energy ESWT (n = 48) | Sham Treatment (n = 48) |
|---|---|---|---|
| Sex, No. (%) | | | |
| Men | 13 (27) | 16 (33) | 28 (58) |
| Women | 35 (73) | 32 (67) | 20 (42) |
| Age, mean (SD), y | 51.6 (8.5) | 47.3 (8.5) | 52.3 (9.8) |
| ESWT location, No. (%) | | | |
| Supraspinatus | 42 (88) | 41 (85) | 43 (90) |
| Infraspinatus | 6 (12) | 7 (15) | 4 (8) |
| Teres minor | 0 | 0 | 0 |
| Subscapularis | 0 | 0 | 1 (2) |
| Calcific deposit size, mean (SD), $mm^2$ | 182 (135.0) | 195 (166.0) | 128 (112.0) |
| Deposit classification, No. (%) | | | |
| Type I | 34 (71) | 30 (63) | 32 (67) |
| Type II | 14 (29) | 18 (37) | 16 (33) |
| Type III | 0 | 0 | 0 |
| Affected side, No. (%) | | | |
| Right | 28 (58) | 28 (58) | 27 (56) |
| Left | 20 (42) | 20 (42) | 21 (44) |
| Pain duration, mean (SD), mo | 42.6 (23.2) | 42.8 (25.2) | 41.3 (28.6) |
| CMS score, mean (SD), points (0-100 scale) | | | |
| Total | 60 (11.0) | 62.7 (14.0) | 64.2 (12.8) |
| Pain | 4.8 (2.7) | 5.9 (3.3) | 5.1 (2.8) |
| ADL | 10.9 (2.9) | 11.9 (3.3) | 12.0 (3.0) |
| Range of motion | 26.7 (5.5) | 26.22 (6.7) | 28.0 (6.1) |
| Power | 17.8 (3.9) | 18.6 (3.7) | 18.9 (4.4) |
| VAS score for pain, mean (SD), points (0-10 scale) | 6.5 (1.3) | 5.7 (1.9) | 5.6 (1.6) |

Abbreviations: ADL, activities of daily living; CMS, Constant and Murley Scale; ESWT, extracorporeal shock wave therapy; VAS, visual analog scale.

## RESULTS

A total of 144 patients (48 per group) were treated as randomized according to the study protocol (Figure). The required number of pulses per treatment was achieved in all cases. Baseline characteristics of the sample are presented in TABLE 1. Only 10 patients were lost to follow-up (7%) prior to the 6-month end point, but considerably more were lost to follow-up after that.

The method of Berger and Exner[32] provided strong support against selection bias; comparing baseline CMS values with conditional probabilities that the next treatment is high energy or low energy given knowledge of the sequence of prior allocations within the randomization block, we obtained Pearson correlation coefficients of 0.03 and –0.01, respectively. The 3 Kruskal-Wallis tests comparing the primary outcome measure across the centers for each of the 3 treatment groups separately showed no center effect ($P\geq.09$ for all), with similar results from analysis of covariance. Alternative evaluation of group comparisons with a respective permutation test yielded similarly nonsignificant results.

### Primary Outcome Measure

The means of the 6-month CMS scores are presented in TABLE 2. In this pri-

mary analysis, both high-energy and low-energy interventions were superior to sham treatment, and in a secondary analysis the high-energy intervention appeared to be superior to the low-energy intervention.

The various components of the score (ie, pain, activities of daily living, range of motion, and power) showed similar patterns of results.

### Secondary Outcome Measures

TABLE 3 presents the results of both the 3-month and 12-month CMS data, which generally parallel those of the 6-month data. Use of other imputation techniques did not substantially change the pattern of results for the 12-month results (data not shown).

TABLE 4 presents the 3-, 6-, and 12-month VAS pain scores as well as radiographic results. Similar to the CMS scores, patients in the high-energy group had significantly less pain than those in the low-energy group, but both groups reported significantly less pain than those in the sham treatment group 6 months after intervention. At 3 and 12 months after intervention, no significant differences in VAS score were observed for the low-energy vs sham treatment groups.

**Table 2.** Six-Month CMS Scores for Groups Receiving High-Energy ESWT, Low-Energy ESWT, and Sham Treatment

| Outcome Measure | Mean Change From Baseline (95% CI) | | | Between-Group Difference (95% CI) | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Group 1 (High-Energy) | Group 2 (Low-Energy) | Group 3 (Sham Treatment) | Group 1 vs Group 3 | *P* Value | Group 2 vs Group 3 | *P* Value | Group 1 vs Group 2 | *P* Value |
| No. of patients | 47 | 46 | 41 | | | | | | |
| Total CMS score, points | 31.0 (26.7 to 35.3) | 15.0 (10.2 to 19.8) | 6.6 (1.4 to 11.8) | –24.4 (–31.0 to –17.8) | <.001 | –8.4 (–15.4 to –1.4) | <.001 | –16.0 (–22.9 to –10.8) | <.001 |
| Pain | 8.7 (7.6 to 9.8) | 3.7 (2.5 to 4.9) | 1.1 (–0.2 to 2.5) | 7.6 (5.9 to 9.3) | <.001 | 2.6 (0.8 to 4.4) | .006 | –5.0 (–6.7 to –3.4) | <.001 |
| ADL | 7.5 (6.5 to 8.5) | 3.0 (1.8 to 4.3) | 0.3 (–1.0 to 1.6) | 7.2 (5.6 to 8.8) | <.001 | 2.8 (1.0 to 4.6) | .003 | –4.5 (–6.1 to –2.8) | <.001 |
| Range of motion | 10.2 (8.6 to 11.9) | 5.3 (3.4 to 7.1) | 1.4 (–0.9 to 3.7) | 8.8 (6.0 to 11.6) | <.001 | 3.9 (0.9 to 6.8) | .01 | –4.9 (–7.4 to –2.5) | <.001 |
| Power | 5.9 (4.7 to 7.1) | 3.2 (2.0 to 4.5) | 1.1 (–0.2 to 2.4) | 4.8 (3.1 to 6.6) | <.001 | 2.2 (0.4 to 4.0) | .02 | –2.7 (–4.4 to –0.9) | .003 |
| Proportion of patients with 30% improvement | 0.89 (0.77 to 0.96) | 0.41 (0.27 to 0.57) | 0.17 (0.07 to 0.32) | 0.72 (0.55 to 0.84) | <.001 | 0.24 (0.05 to 0.42) | .02 | 0.48 (0.30 to 0.63) | <.001 |

Abbreviations: ADL, activities of daily living; CI, confidence interval; CMS, Constant and Murley Scale; ESWT, extracorporeal shock wave therapy.

**Table 3.** Three-Month and 12-Month CMS Scores for Groups Receiving High-Energy ESWT, Low-Energy ESWT, and Sham Treatment

| Outcome Measure | Mean Change From Baseline (95% CI) | | | Between-Group Difference (95% CI) | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Group 1 (High-Energy) | Group 2 (Low-Energy) | Group 3 (Sham Treatment) | Group 1 vs Group 3 | *P* Value | Group 2 vs Group 3 | *P* Value | Group 1 vs Group 2 | *P* Value |
| **3-Month Scores** | | | | | | | | | |
| No. of patients | 44 | 46 | 42 | | | | | | |
| Total CMS score, points | 26.2 (22.3 to 30.2) | 16.6 (11.8 to 21.0) | 9.8 (5.1 to 14.5) | –16.4 (–22.5 to –10.3) | <.001 | –6.6 (–13.1 to –0.1) | .047 | –9.6 (–15.8 to –3.4) | .003 |
| Pain | 7.2 (6.0 to 8.4) | 3.7 (2.5 to 5.0) | 2.4 (1.1 to 3.8) | 4.8 (3.0 to 6.6) | <.001 | 1.3 (–0.5 to 3.2) | .15 | –3.5 (–5.2 to –1.7) | <.001 |
| ADL | 6.5 (5.1 to 7.8) | 3.9 (2.7 to 5.1) | 1.9 (0.7 to 3.2) | 4.5 (2.7 to 6.3) | <.001 | 2.0 (0.2 to 3.7) | .03 | –2.6 (–4.4 to –0.8) | .006 |
| Range of motion | 7.5 (5.7 to 9.3) | 5.5 (3.7 to 7.4) | 3.3 (1.1 to 5.4) | 4.3 (1.5 to 7.0) | .004 | 2.3 (–0.6 to 5.1) | .12 | –2.0 (–4.6 to 0.6) | .14 |
| Power | 5.1 (3.8 to 6.3) | 3.2 (2.1 to 4.3) | 1.9 (0.7 to 3.1) | 3.2 (1.5 to 4.9) | <.001 | 1.4 (–0.3 to 3.0) | .11 | –1.9 (–3.5 to –0.2) | .03 |
| Proportion of patients with 30% improvement | 0.77 (0.62 to 0.89) | 0.40 (0.26 to 0.55) | 0.21 (0.10 to 0.37) | 0.56 (0.36 to 0.71) | <.001 | 0.19 (0.01 to 0.36) | .07 | 0.37 (0.18 to 0.55) | <.001 |
| **12-Month Scores** | | | | | | | | | |
| No. of patients | 35 | 44 | 32 | | | | | | |
| Total CMS score, points | 31.6 (27.3 to 36.0) | 17.7 (13.2 to 22.3) | 13.7 (8.4 to 19.0) | –17.9 (–24.7 to –11.1) | <.001 | –4.1 (–11.0 to 2.8) | .24 | –13.9 (–19.7 to –8.3) | <.001 |
| Pain | 10.0 (9.4 to 10.6) | 4.2 (3.1 to 5.3) | 4.4 (2.9 to 5.9) | 5.6 (4.0 to 7.2) | <.001 | –0.2 (–2.0 to 1.7) | .86 | –5.8 (–7.1 to –4.5) | <.001 |
| ADL | 7.9 (7.1 to 8.7) | 3.5 (2.2 to 4.7) | 3.1 (1.8 to 4.4) | 4.8 (3.3 to 6.4) | <.001 | 0.4 (–1.4 to 2.2) | .68 | –4.4 (–6.0 to –2.9) | <.001 |
| Range of motion | 11.7 (9.9 to 13.5) | 6.6 (4.7 to 8.6) | 4.3 (2.3 to 6.2) | 7.4 (4.8 to 10.1) | <.001 | 2.4 (–0.4 to 5.1) | .09 | -5.1 (–7.8 to –2.3) | <.001 |
| Power | 6.3 (5.0 to 7.6) | 3.6 (2.3 to 4.8) | 2.8 (1.1 to 4.4) | 3.5 (1.5 to 5.6) | .001 | 0.8 (–1.2 to 2.9) | .42 | –2.7 (–4.5 to –0.9) | .005 |
| Proportion of patients with 30% improvement | 0.94 (0.81 to 0.99) | 0.45 (0.30 to 0.61) | 0.22 (0.09 to 0.40) | 0.72 (0.53 to 0.85) | <.001 | 0.23 (0.01 to 0.43) | .05 | 0.49 (0.31 to 0.64) | <.001 |

Abbreviations: ADL, activities of daily living; CI, confidence interval; CMS, Constant and Murley Scale; ESWT, extracorporeal shock wave therapy.

Complete disappearance of the calcific deposit was observed in 60% of the patients in the high-energy group after 6 months and in 86% after 12 months. In the low-energy group, complete disappearance was observed in 21% and 37%, respectively. In the sham treatment group, complete disappearance was observed in 11% after 6 months and in 25% after 12 months. Finally, it appeared that more patients in the sham treatment group used additional therapies after 6 months (Figure 1).

### Adverse Effects

Adverse effects were assessed by clinical examination, ultrasound imaging, and by patient questionnaire directly after the ESWT procedure and after every follow-up visit. All findings were recorded on standardized forms. Patients were explicitly asked to report any reddening of the skin, swelling, petechiae, reaction to the anesthetic used, bleeding, acute bursitis, or syncope occurring after the intervention. In addition, patients also were asked whether they had experienced any other adverse effects. Unexpected or severe adverse events were to be reported separately, but none occurred.

Pain during treatment was analyzed separately. In the group receiving high-energy ESWT, 20 patients reported moderate pain and 16 reported severe pain. Eight of those reporting severe pain required intravenous analgesics during intervention. Ten patients in the high-energy group had insignificant or no pain during the ESWT procedure. In the group receiving low-energy ESWT, moderate pain was reported by 22 patients and severe pain by 5; 2 of those reporting severe pain required intravenous pain medication. Twenty-one patients in the low-energy group reported slight or no pain.

In the sham treatment group, 25 patients reported some sensation of pain. Four had severe pain and 1 required additional intravenous pain medication. Insignificant or no pain sensation was observed in 23 cases.

Petechiae, bleeding, hematoma, or erythema were found directly after the treatment in 36 patients in the high-energy group, 32 patients in the low-energy group, and 8 patients in the sham treatment group.

No clinically significant adverse effects (including neurologic disorders, tendon rupture, infection, bone edema, aseptic necrosis, or muscle hematoma) were observed in any of the patients at any point in time.

## COMMENT

Shoulder pain due to calcific tendonitis is a common problem, for which conservative therapy is sometimes ineffective.[1,5] In these cases, ESWT has been proposed as an alternative to operative procedures,[21,24,33-35] although methodological flaws have limited the conclusions of previous studies.[12] In our study, we found a significant clinical benefit for both high- and low-energy ESWT at 6 months, with significantly better outcomes associated with high-energy ESWT. Patients in the sham treatment group showed a previously demonstrated spontaneous improvement.[4] Nonetheless, they required more pain medication than patients in the 2 ESWT groups and were more likely to undergo surgery during follow up.

Some authors have stressed the importance of stone removal in the therapy of nephrolithiasis, while others have suggested a need for complete disintegration of the calcified deposits around

**Table 4.** Three-Month, 6-Month, and 12-Month VAS Pain Scores and Calcific Deposit Sizes for Groups Receiving High-Energy ESWT, Low-Energy ESWT, and Sham Treatment

| | Mean Change From Baseline (95% CI) | | | Between-Group Difference (95% CI) | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Outcome Measure | Group 1 (High-Energy) | Group 2 (Low-Energy) | Group 3 (Sham Treatment) | Group 1 vs Group 3 | *P* Value | Group 2 vs Group 3 | *P* Value | Group 1 vs Group 2 | *P* Value |
| **3-Month Results** | | | | | | | | | |
| No. of patients | 44 | 46 | 42 | | | | | | |
| VAS score for pain (0-10 scale) | −5.0 (−5.7 to −4.2) | −2.7 (−3.3 to −2.1) | −1.8 (−2.5 to −1.1) | 3.2 (2.2 to 4.2) | <.001 | 0.9 (0.0 to 1.8) | .06 | 2.3 (0.5 to 1.3) | <.001 |
| Calcific deposit size, mm$^2$ | −128.9 (−170.0 to 87.7) | −56.3 (−106.7 to 5.8) | −30.3 (−53.7 to −7.0) | 98.6 (51.8 to 145.4) | <.001 | 26.0 (−29.1 to 81.1) | .35 | 72.6 (8.2 to 141.1) | .03 |
| **6-Month Results** | | | | | | | | | |
| No. of patients | 47 | 46 | 41 | | | | | | |
| VAS score for pain (0-10 scale) | −5.5 (−6.2 to −4.8) | −2.4 (−3.1 to 1.7) | −1.1 (−1.8 to −0.5) | 3.7 (2.7 to 4.7) | <.001 | 1.3 (0.4 to 2.2) | .008 | 3.1 (2.5 to 4.3) | <.001 |
| Calcific deposit size, mm$^2$ | −152.8 (−195.0 to −110.0) | −77.7 (−130.0 to −24.9) | −41.0 (−66.0 to −16.1) | 111.8 (63.2 to 160.5) | <.001 | 36.7 (21.2 to 94.6) | .21 | 75.1 (9.0 to 144.3) | .03 |
| **12-Month Results** | | | | | | | | | |
| No. of patients | 35 | 44 | 32 | | | | | | |
| VAS score for pain (0-10 scale) | −5.6 (−6.3 to −4.9) | −2.6 (−3.2 to −1.9) | −1.9 (−2.7 to −1.2) | 3.7 (2.7 to 4.7) | <.001 | 0.7 (−0.3 to 1.7) | .18 | 3.0 (2.3 to 3.7) | <.001 |
| Calcific deposit size, mm$^2$ | −162.2 (−204.0 to −120.0) | −91.5 (−148.0 to −35.1) | −46.8 (−74.3 to −19.3) | 115.4 (65.4 to 165.4) | <.001 | 44.7 (−17.6 to 107.0) | .16 | 70.7 (1.9 to 139.5) | .04 |

Abbreviations: CI, confidence interval; ESWT, extracorporeal shock wave therapy; VAS, visual analog scale.

joints.[36] We observed a complete disappearance of the deposit in 60% of patients 6 months after receiving high-energy ESWT, a nearly 3-fold greater rate of complete disintegration than that observed in those who received sham treatment. Although some authors have discussed the potential of extracorporeal shock waves for disintegrating calcified deposits of the rotator cuff, the mechanisms remain unclear.[37-39]

Several studies have found a correlation between the applied energy of each shock wave and the rate of disintegration,[23,25] assuming that the shock wave is carefully focused.[40] At present, however, it is unclear which parameters of shock waves are most related to resorption of the deposit. The "energy flux density" parameter is generally assumed to be the primary parameter for physical and biological effects.[41] For instance, simply doubling the number of applied shock waves does not appear to improve the likelihood of eliminating tendon calcification or of improving clinical outcomes.[24,25] Our results similarly suggest that the energy level seems to be a more important parameter. The high-energy and low-energy groups received the same total acoustic energy but showed different clinical and radiological outcomes. In addition to the number of shock waves and energy level, the frequency of shock waves may have an influence. Recent studies of kidney stones found that fragmentation efficiency, due to cavitation effects, was significantly enhanced at a delay of between 400 and 250 microseconds between shock waves.[42] These findings support the idea that cavitation effects may be related to the disintegrating effect of ESWT.[39,43] It also seems likely that ESWT may be more effective for calcifying tendonopathy than for impingement syndromes that do not involve any calcified masses.[44,45]

We found no serious adverse effects of ESWT. As in previous studies,[23,33,35,46] some patients in our study did complain of petechial bruising, subcutaneous hematoma, or skin reddening immediately after treatment, but in all cases these had resolved by 3 months. It is possible that different shock wave generators may vary in their physical parameters, and thus in their likelihood of causing bruising.

While studies in rabbits have revealed some short-term tendon pathology associated with ESWT energy levels of at least 0.6 mJ/mm,[2,47] neither tendon nor cartilage of joints has been found to be injured by shock waves lower than this energy level.[48,49] Although we did not perform imaging studies to detect these potential adverse effects, neither tendon ruptures nor aseptic necrosis of the humeral head[50] were reported. Long-term observations 4 years after high-energy treatment found neither tendon lesions nor other adverse effects due to shock waves in patients who later underwent surgery.[51,52] It is possible that ESWT could be less expensive than surgery for treatment of calcific tendonitis of the shoulder.[53]

Our results have 2 important limitations. First, our findings may be limited by the different amounts of intravenous sedation used in the treatment groups, which was confounded with the effects of the active therapy and the amount of shock wave energy. It is unlikely that intravenous sedation alone, however, may have influenced this chronic pain condition. Second, because of the high drop-out rates after 6 months, the 12-month data should be interpreted with caution.

Our findings need to be confirmed in high-quality randomized clinical trials with different treatment protocols and treatment parameters, including the number of shock waves, their frequency, and their energy levels. Further studies also are necessary to analyze the long-term prognosis, and also should examine less-systemic forms of anesthesia, including regional nerve block or local anesthesia.

In summary, we found evidence for a beneficial effect of high-energy ESWT over 6 months, compared with sham treatment. High-energy ESWT appears to be more effective than low-energy ESWT, but threshold energy has yet to be defined.

**Author Affiliations:** Department of Orthopedic Surgery and Sportstraumatology (Drs Gerdesmeyer and Lampe), Institute of Medical Statistics and Epidemiology (Dr Wagenpfeil), and Department of Radiology (Dr Wörtler), Technical University Munich, Munich, Germany; Department of Orthopedic Surgery, University of Regensburg, Bad Abbach, Germany (Dr Haake); Department of Orthopedic Surgery, Ludwig Maximilian University Munich, Munich, Germany (Dr Maier); Department of Orthopedic Surgery, Ruprecht-Karls-University Heidelberg, Heidelberg, Germany (Dr Loew); Department of Orthopedic Surgery, University of Homburg, Homburg/Saar, Germany (Dr Seil); Department of Orthopedic Surgery, University of Innsbruck, Innsbruck, Austria (Dr Handle); Department of Orthopedic Surgery, University of Bonn, Bonn, Germany (Dr Gassel); and Department of Orthopedic Surgery, Johannes Gutenberg University School of Medicine, Mainz, Germany (Dr Rompe).

**Author Contributions:** Dr Gerdesmeyer, as principal investigator of this study, had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analyses.
*Study concept and design:* Gerdesmeyer, Wagenpfeil, Haake.
*Acquisition of data:* Loew, Seil.
*Analysis and interpretation of data:* Gerdesmeyer, Wagenpfeil, Maier, Wörtler, Lampe, Handle, Gassel, Rompe.
*Drafting of the manuscript:* Gerdesmeyer, Haake, Loew.
*Critical revision of the manuscript for important intellectual content:* Gerdesmeyer, Wagenpfeil, Maier, Wörtler, Lampe, Seil, Handle, Gassel, Rompe.
*Statistical expertise:* Gerdesmeyer, Wagenpfeil, Haake.
*Administrative, technical, or material support:* Maier, Loew, Wörtler, Lampe, Seil, Handle, Gassel.
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