Extracorporeal Shock Wave Therapy in the Treatment of Calcific Tendinitis of the Rotator Cuff

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Background: Low-energy extracorporeal shock wave therapy is an alternative treatment, with limited evidence for effectiveness, for calcific tendinitis of the rotator cuff.

Hypothesis: Objective localization of the calcium deposit by 3-dimensional, computer-assisted navigation reveals superior clinical and radiographic outcomes compared to localization through patient-to-therapist feedback.

Study Design: Randomized controlled clinical trial; Level of evidence, 1.

Methods: A prospective, randomized, single-blind study was carried out on 50 patients. The population was divided into 2 groups of equal numbers (navigation group and feedback group). In all patients, treatment-resistant pain was evident for longer than 6 months. A total of 3 therapy sessions of constant low-energy focused shock wave therapy was administered in weekly intervals in both groups. Local anesthesia was not applied. Radiographs and clinical assessment, including the Constant and Murley shoulder scoring system and the visual analog scale for pain, were performed both before therapy and after 12 weeks. In the navigation group, the calcium deposit was localized using a radiographically guided, 3-dimensional, computer-assisted device. The feedback group was treated after locating the point of maximum tenderness through palpation by the therapist with feedback from the patient.

Results: Both groups had significant improvements in the Constant and Murley score and the visual analog scale after 12 weeks. The results from the navigation group were statistically significantly superior to those of the feedback group. In the navigation group, 6 calcium deposits disappeared and 9 altered, compared to 1 disappearance and 12 alterations in the feedback group. No severe complications occurred.

Conclusion: Three-dimensional, computer-assisted navigation reveals significantly better results and is therefore recommended when extracorporeal shock wave therapy is used in the treatment of calcific tendinitis of the rotator cuff.

Keywords: extracorporeal shock wave therapy (ESWT); calcific tendinitis; shoulder; navigation

Calcific tendinitis (CT) of the rotator cuff is a common enthesopathy of the shoulder. It is a benign disease of unknown duration. The progress of this disorder passes through 4 phases and ends with complete restitution. Women tend to be more frequently affected than men. Most patients complain about impingement symptoms, including interrupted sleep and pain when working with the arm of the diseased shoulder elevated. The diagnosis is established by clinical examination, radiographs in 3 planes (Figures 1 and 2), ultrasound, and MRI. A link between the occurrence of CT with the HLA complex[5] has not yet been proved. Nonoperative treatment, such as physical therapy, iontophoresis, ultrasound, deep friction, and local and systemic application of noninflammatory drugs, is the first line of therapy for CT. In case of treatment-resistant symptoms, arthroscopic and open procedures are available to curette the calcium deposit, and an additional subacromial decompression can be performed if necessary. Extracorporeal shock wave therapy (ESWT) has been recommended as a second-line therapy, with limited evidence of effectiveness as a treatment option before surgery.[3,6,13,15]

Before objective localization of the calcium deposit with ultrasound or radiographs, the patient assists the therapist in locating the point of maximum shoulder tenderness through palpation. Computer-assisted navigation is now available to locate the calcified lesion radiographically during ESWT, and this new technique may improve the effectiveness of treating chronic CT with ESWT.

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No potential conflict of interest declared.

The American Journal of Sports Medicine, Vol. 33, No. 9
DOI: 10.1177/0363546504273052

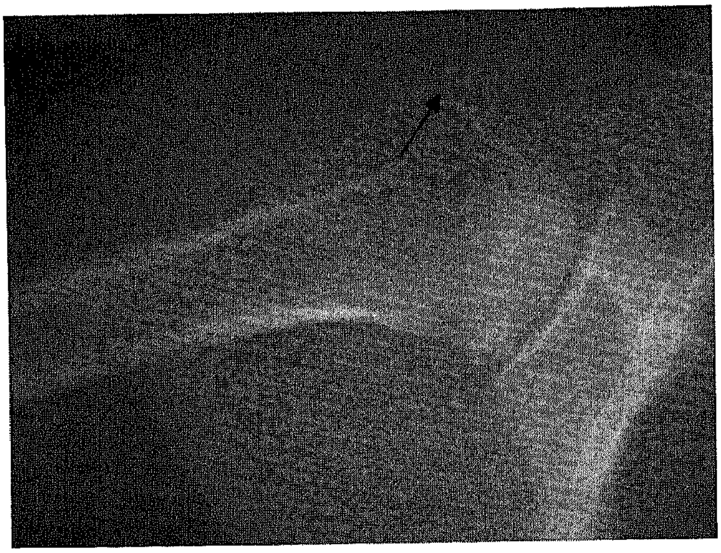

Figure 1. Radiograph before extracorporeal shock wave therapy of a shoulder (male patient, 54 years of age) with calcific tendinitis (arrow).

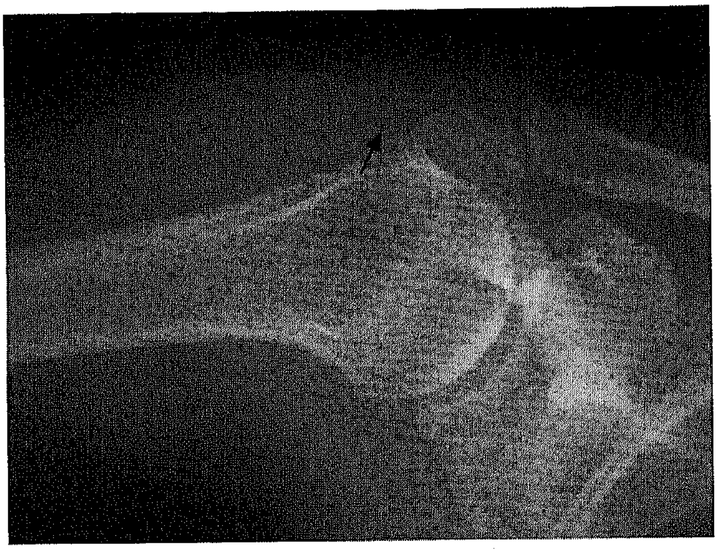

Figure 2. Radiograph of a shoulder (without calcium deposit; male patient, 54 years of age) 12 weeks after extracorporeal shock wave therapy.

Shock waves are sound waves with high-pressure differences of very short duration. At the interface of anatomical structures with different acoustic impedances, high-pressure differences occur.[9,10,14] The precise pathway of this mechanism is not yet fully understood.

Maier et al[8] and Gerdesmeyer et al[6] demonstrated the effectiveness of shock waves in treating CT. Haake et al[7] proved that radiographically assisted localization of the calcium deposit is clinically superior for treatment of the supraspinatus insertion at the humeral head. Gerdesmeyer et al[6] had the best results in radiographically assisted localization by applying high-energy shock waves. Although most studies revealed that shock wave therapy (SWT) is a safe procedure, Durst et al[4] reported a possible case of avascular necrosis (AVN) of the humeral head after SWT. To our knowledge, no other study reported AVN in the treatment of soft tissue disorders with SWT.

In this study, we analyzed the outcome of low-energy SWT by using a radiographically guided, 3-dimensional, computer-assisted navigation device to localize the calcium deposit, and we compared the results to conventional localization through patient feedback.

MATERIALS AND METHODS

A total of 50 patients took part in a prospective, randomized, patient-blind study trial. The authors' department is a center for ESWT in eastern Austria. Patients were recruited from the department's outpatient clinic after passing the inclusion and exclusion criteria (Table 1). The population was divided into 2 groups of equal numbers, according to randomization performed by the department of medical statistics at the authors' institution. The setup in the treatment room was the same for both groups. The cohorts were scheduled at different times to ensure that the individuals within the cohorts would not contact each other. All patients had CT of the supraspinatus tendon, verified radiographically. Before the first treatment session and after 12 weeks, patients were clinically tested with the visual analog scale (VAS) for pain and with the Constant and Murley shoulder scoring system (CMS).[1] Radiographs were made before the first treatment session and at the 12-week follow-up meeting. The radiographs were then analyzed by an independent observer, who compared differences and assigned grades according to a 4-level evaluation system. No change in the radiographs was graded as 4, a 3 indicated slight alteration of the calcium deposit, reduction in deposit size and radiographic density was graded as 2, and a 1 was given if the calcium deposit was no longer evident. Both groups were treated with the same lithotripter (Modulith SLK, Storz Medical Products, Kreuzlingen, Switzerland). A contact gel was applied between the shoulder and the coupling unit of the lithotripter (Gerosonic, Geropharmazeutica, Vienna, Austria). Local anesthesia was not applied. In both groups, focused low-energy shock waves (1000 impulses of 0.08 mJ/mm^2 with a frequency of 4 Hz) were administered 3 times in weekly intervals. In group 1, the patient and therapist located the point of maximum tenderness by palpation, and in group 2, a radiographically guided, 3-dimensional, computer-assisted navigation device (Lithotrack system, Storz Medical Products) was used.

In group 1, after the point of maximum tenderness was located, the area was marked with a ballpoint pen. Through a window of the coupling unit of the lithotripter, the marked area was located as the shock wave focus. The angle and distance between the coupling unit and shoulder were adjusted until the patient reported pain at the exact point of maximum tenderness. In group 2, the Lithotrack device was used. The calcium deposit was located in the center of a crosshairs by fluoroscopy in 2 planes. The computer calculated the angle and distance to provide maximum precision. On a monitor located on the navigation device, the distance of the shock wave focus to the deposit was stated in millimeters.

TABLE 1
Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Mature skeleton	Tumor
Typical pain	Pregnancy
Symptoms >6 months	Local infection, skin disease, pacemaker
Failed >2 different nonoperative treatments	Osteoarthritis of the shoulder

TABLE 2
Group Characteristics

Variable	Group 1	Group 2
Women/men	15/10	13/12
Age, y[a]	52.96 ± 8.77	52.4 ± 7.74
VAS before ESWT[a]	68.36 ± 15.26	65.96 ± 21.71
VAS at follow-up[a]	33.36 ± 20.05	18.21 ± 21.32
CMS before ESWT[a]	55.64 ± 12.5	49.4 ± 12.33
CMS at follow-up[a]	73.0 ± 16.25	79.48 ± 15.1

[a]Values represent means ± SDs. VAS, visual analog scale for pain; ESWT, extracorporeal shock wave therapy; CMS, Constant and Murley shoulder scoring system.

Results regarding pain were considered excellent when the VAS was less than 15 and good when it was less than 30. Regarding function, results were considered excellent when the CMS was higher than 85 and good when the CMS was higher than 70.

Statistical Methods

Descriptive statistics was calculated first. To determine the differences between the groups, analyses of covariance for the VAS and CMS were performed. For the radiographic outcome, a logistic regression was used to detect differences between the groups. Statistical significance was set at $P < .05$.

RESULTS

A total of 50 patients completed the investigation protocol; 23 left and 27 right shoulders were analyzed (Table 2). The mean age of the population was 52.68 (±8.19) years. The mean overall CMS score was 52.52 (±12.69), and the mean VAS score was 67.16 (±18.61) before the first therapy.

Visual Analog Scale

The VAS in group 1 improved over 12 weeks statistically from 68.36 (±15.26) to 33.36 (±20.05). In group 2, pain was reduced from 65.96 (±21.71) to 18.21 (±21.32). Both groups revealed statistically significant improvement ($P < .0001$ for both groups). The difference within the groups was also significant ($P = .0236$). In group 2, 15 patients attained excellent results, compared to 5 patients in group 1. Good results were recorded in 3 patients in group 2 and 9 patients in group 1.

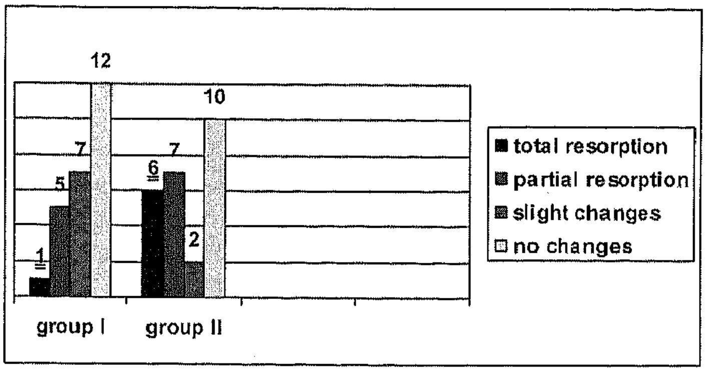

Figure 3. Radiographic outcomes. Numerals above bars indicate the number of patients per outcome.

Constant and Murley Score

The CMS in group 1 improved by 17.36 (±15.41) points, from 55.64 (±12.5) at the beginning of ESWT to 73.0 (±16.25) after 12 weeks. In group 2, an improvement of 30.08 (±14.23) points, from 49.4 (±12.33) to 79.48 (±15.1), was recorded. Both groups revealed statistically significant improvement ($P < .001$). The scores in group 2 were statistically significantly superior to those in group 1 ($P = .0208$). In group 1, excellent shoulder function was attained in 10 patients, compared to 13 patients in group 2. Good shoulder function was observed in 5 patients in group 1 and 6 patients in group 2.

Radiographs

In group 2, total resorption was recorded in 6 patients, compared to 1 patient in group 1; 7 patients in group 2 had an extensive reduction in size and radiographic density of the calcium deposit, compared to 5 patients in group 1. All data are listed in Figure 3. The group treated with Lithotrack revealed statistically significantly better results than did the feedback group ($P = .041$). The mean time of fluoroscopy was 7 seconds (range, 5-14 seconds) per treatment.

Patients with a complete dissolution of the calcium deposit had the overall best clinical results. The mean VAS after 12 weeks was 4 (range, 0-16), and the mean CMS improved to 88.57 (range, 79-98). The percentages of patients with excellent or good results in the VAS and the CMS were 64% and 72%, respectively.

Complications or severe side effects, particularly signs of AVN, were not recorded.

DISCUSSION

Schmitt et al[11] and Speed et al[12] researched the effectiveness of SWT with low-energy shock waves in the treatment of tendinitis of the supraspinatus muscle. In both investigations, a randomized, placebo-controlled prospective study trial was assessed, revealing that both the placebo and active groups improved significantly. The difference between the groups was not significant; therefore, SWT was not recommended for non-CT of the rotator cuff.

Cosentino et al[2] analyzed the outcome of SWT in the treatment of CT in a single-blind, randomized, placebo-controlled investigation of 70 patients. Assessments were performed with the CMS, and radiographs demonstrated 69% clinical improvement, 31% for total and 40% for partial resorption of the calcium deposit in the active group, whereas the placebo group remained unchanged. Cosentino et al[2] stated that SWT should be applied in treatment-resistant CT and administered before surgery. Maier et al[8] performed a prospective controlled study of 97 patients, of which 36 had CT. Three to 5 treatment sessions were applied, and follow-up was assessed 5 months after treatment with the Short Form–36 (SF-36). The study revealed evidence of short-term analgesia after SWT. The subjective satisfaction and comfort scores measured with the SF-36 demonstrated significant improvement in all variables. The number of sessions had no influence on the outcome.

In a prospective, randomized trial, Daecke et al[3] analyzed the outcome after treatment with SWT of 115 patients with evident CT. One treatment session was compared to 2 sessions, with an interval of 1 week. Roughly 60% of all patients profited from ESWT within 6 months after treatment. Patients with disappearance of the deposit in radiographs had higher increases in the CMS. According to these findings, Daecke et al[3] stated that there is evidence of the effectiveness of high-energy SWT. Wang et al[15] included 44 subjects in a prospective and placebo-controlled trial. After a follow-up of 2 years, 60% of the patients were clinically free of pain, and 57% of the population had no evidence of CT according to radiographs. Wang et al[15] reported observing a correlation between the dissolution of the deposit and the clinical benefit of high-energy SWT and thus agreed with Daecke et al.[3] Haake et al[7] revealed in a single-blind, prospective, randomized investigation of 50 patients that the exact localization of the calcium deposit is more effective clinically and radiographically than is treating the insertion of the supraspinatus tendon. They highly recommended the exact focusing on the deposit. Gerdesmeyer et al[6] showed that high-energy shock wave treatment is superior to low-energy SWT, but both modalities were statistically significantly superior to placebo treatment in a prospective, double-blind, randomized study trial. The results of our investigation revealed a statistically significant improvement in the navigation group for all tested variables. We agree with Haake et al[7] that ESWT for the treatment of CT should be carried out with a navigation system, if available. In agreement with Wang et al[15] and Daecke et al,[3] we observed the best clinical results in patients with a complete dissolution of the calcium deposit. Overall, both groups attained statistically significant improvement ($P < .001$ for all variables) 12 weeks after SWT. The difference within the groups was statistically significant in all variables as well. Wölk and Wittenberg[16] investigated 159 patients for a mean duration of symptoms of 49 months. A resorption of the calcium deposit after nonoperative therapy was observed after a mean interval of 60 months in 67% of the population. After 5 years, 68% of the population was free of symptoms, attaining a CMS of 80 to 100. Compared with these data, 64% of patients in this investigation attained excellent or good results in the VAS and 72% attained excellent or good results in the CMS after 12 weeks of therapy. The limits of this investigation were the short follow-up period and the small number of patients. The short follow-up limited our ability to document later recurrence or to detect the late occurrence of complications such as AVN. Another limitation was the lack of a placebo group, which prevented us from comparing the results of both forms of ESWT to any other spontaneous improvement that might have occurred during the 12-week period.

According to published results and from our experience, we recommend focused low-energy SWT for CT.

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