

Shock Wave Therapy Versus Conventional Surgery in the Treatment of Calcifying Tendinitis of the Shoulder

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A prospective quasirandomized study was performed to compare the effects of surgical extirpation (Group I, 29 patients) with the outcome after high-energy extracorporeal shock wave therapy (Group II, 50 patients; 3000 impulses of an energy flux density of 0.6 mJ/mm²) in patients with a chronic calcifying tendinitis in the supraspinatus tendon. Symptoms and demographic data of the two groups were comparable. According to the University of California Los Angeles Rating System, the mean score in Group I was 30 points with 75% good or excellent results after 12 months, and 32 points with 90% good or excellent results after 24 months. Radiologically, there was no calcific deposit in 85% of the patients after 1 year. In Group II, the mean score was 28 points with 60% good or excellent results after 12 months, and 29 points with 64% good or excellent results after 2 years. Radiologically, complete elimination of the deposit was observed in 47% of the patients after 1 year. Clinically, according to the University of California Los Angeles score, there was no significant difference between both groups at 1 year. At 2 years, there was a significantly better result in Group II. Both groups then were subdivided into patients who had a homogenous deposit as seen on radiographs and patients who had an inho-

mogenous deposit before treatment. Surgery was superior compared with high-energy shock wave therapy for patients with homogenous deposits. For patients with inhomogenous deposits, high-energy extracorporeal shock wave therapy was equivalent to surgery and should be given priority because of its noninvasiveness.

Calcific tendinitis as a source of shoulder pain initially was described more than 100 years ago as *Maladie de Duplay*.⁹ The disease usually is self-limiting and the natural history still is contradictory.^{48,49}

Reports concerning the incidence of the disease are inconsistent. Tendon calcifications have been observed in 2.7% to 20% of patients without pain in their shoulders, whereas in shoulders of patients with chronic periartthritis, calcifying tendinitis has been observed in as many as 17% of patients.^{4,20,32,43,48} Bosworth⁴ described progressive vanishing of the deposits in 9.3% of patients within 3 years after the initial diagnosis. Wagenhäuser⁵² reported that deposits had disappeared in 27.1% of his patients after 10 years.

The treatment of patients with calcific tendinitis typically is conservative. If the pain becomes chronic or intermittent after several months of conservative treatment, surgical removal has been recommended.⁴⁸ Success rates greater than 80% have been reported.²⁹

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Recently, extracorporeal shock wave therapy has shown encouraging preliminary results in the treatment of calcific deposits.^{27,28,41,50} The goal of the current study was to compare the efficiency of open surgery and extracorporeal shock wave application in patients with chronic, symptomatic calcifying tendinitis of the supraspinatus tendon.

MATERIALS AND METHODS

Seventy-nine consecutive patients with a chronic calcifying tendinitis of the supraspinatus tendon were recruited prospectively between 1996 and 1998. All patients had been referred to the authors' institution for recalcitrant shoulder pain by general or orthopaedic practitioners. All patients had a clinical examination and anteroposterior (AP) radiographs, acromial outlet views, sonography and/or magnetic resonance imaging (MRI). The patients were informed about open surgical removal of the deposit and about high-energy extracorporeal shock wave therapy as a nonsurgical alternative. All patients contacted their health insurance companies and asked for reimbursement of the shock wave therapy. In 29 cases, reimbursement was denied and the patients had to undergo surgery. The remaining 50 patients decided to receive shock wave therapy after reimbursement had been offered. The assignment of the patients to either group was done completely independent of the authors' institution.

Inclusion and exclusion criteria were identical. All patients reported in the current study fulfilled the following criteria: Calcareous deposit on standardized AP radiographs of a diameter of at least 10 mm; the morphologic features of the deposit had to be homogenous in appearance and with well defined borders (corresponding to Type I in the Gärtner classification¹³), or inhomogenous in structure with sharp outline or homogenous in structure with no defined border (corresponding to Type II in the Gärtner classification¹³); shoulder pain for more than 12 months; clinical signs of subacromial impingement;^{19,31} unsuccessful conservative therapy in the previous 6 months (Table 1); no evidence of bone-related anatomic outlet impingement or functional outlet impingement as seen on radiographs or MRI scans.

Exclusion criteria were cloudy and transparent appearance of the deposit (Type III according to

Gärtner¹³); radiologic signs of spontaneous resorption (Fig 1); evidence of a Type-III acromial morphologic feature according to Bigliani et al³ on the outlet view of the acromion; evidence of acute subacromial bursitis; evidence of an acromial spur or acromioclavicular osteophytes on the AP radiographs; evidence of rotator cuff tears on MRI scans; evidence of functional impingement of the rotator cuff on sonographs or arthroMRI scans or both; tears of the glenohumeral ligaments of the labrum; hypertrophy of the supraspinatus muscle; dysfunction in the neck (spondylarthritis, cervical disc herniation) or thoracic region (hyperkyphosis, spondylarthritis); prior surgery to the shoulder; local degenerative disease of the shoulder; rheumatoid arthritis; neurologic abnormalities of the upper extremity with calcifying tendinitis; pregnancy; infection; and tumor.

Group I

The patients in Group I underwent surgery as described below. Group I consisted of 29 patients (20 women and 19 men), with a mean age of 53 years (range, 31–68 years), and a mean duration of pain of 36.1 ± 28.6 months (range, 12–60 months; mean, 24 months). There were 19 Type I deposits and 10 Type II deposits according to the Gärtner¹³ classification. The right shoulder was affected in 54% of the patients.

The patient was in a beach chair position with a towel placed under the scapula. With the patient under general anesthesia, the rotator cuff was exposed through a 5 to 6 cm long anterior incision as for an acromioplasty. The deltoid was split parallel to its fibers for no more than 5 cm distal to its acromial attachment to prevent damage to the axillary

TABLE 1. The Methods of Treatment Before Referral to the Hospital

Treatment	Group I n = 29	Group II n = 50
Physiotherapy	29	50
Antiinflammatory drugs	29	43
Cryotherapy	29	38
Infiltration with local anesthetic	29	45
Infiltration with steroids	24	23
Needling	9	18
Radiation therapy	4	8

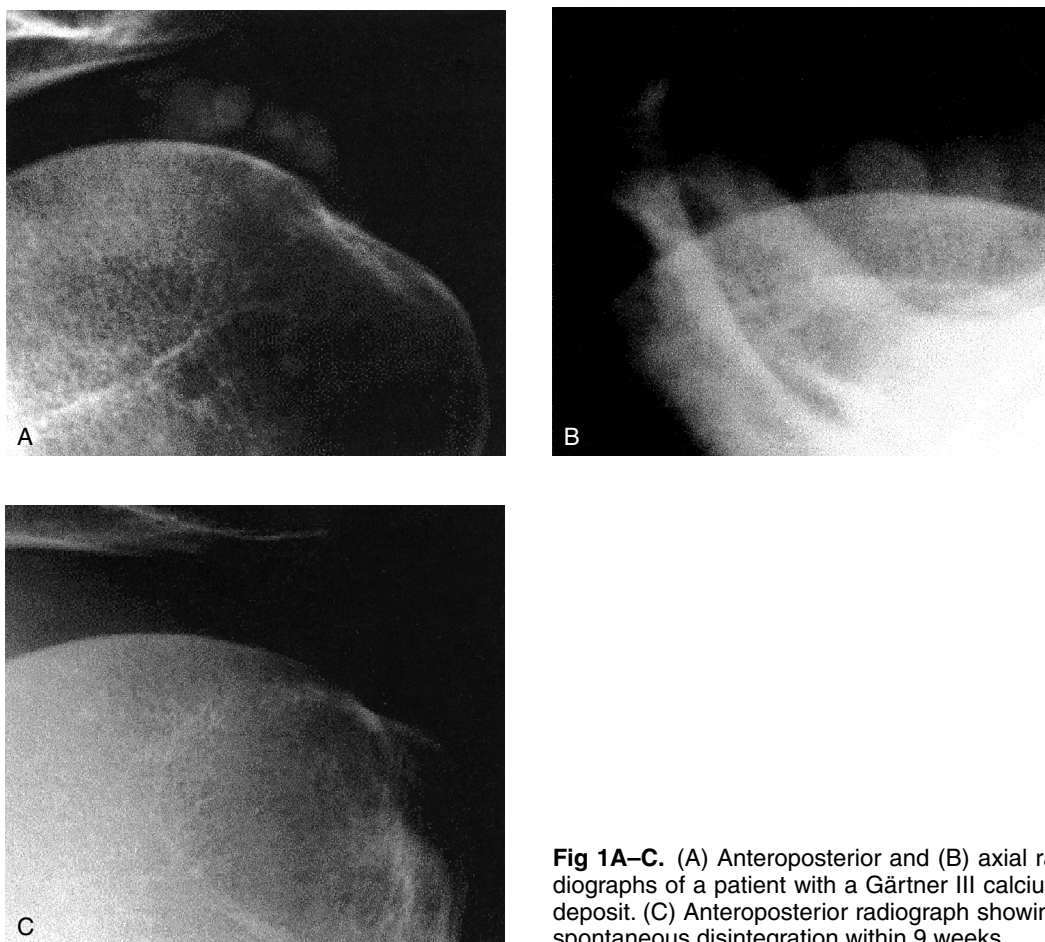


Fig 1A–C. (A) Anteroposterior and (B) axial radiographs of a patient with a Gartner III calcium deposit. (C) Anteroposterior radiograph showing spontaneous disintegration within 9 weeks.

nerve. After partial subdeltoid bursectomy, the rotator cuff was exposed. After identification of the calcium deposit in the supraspinatus tendon macroscopically or by fluoroscopy, the tendon was incised longitudinally and the calcium was removed by curettage. The defect was closed by slowly resorbable sutures. The anterior acromial edge was smoothed with a rasp. A drain was inserted. Then the deltoid and its fascia were reapproximated with a resorbable vicryl suture, the subcutaneous tissues were closed, and a subcuticular nonresorbable suture was applied for the skin. A sterile dressing was applied. After the operation the arm was supported by a sling, and pendulum exercises were started after removal of the drain the day after surgery. During the following 3 days, passive assisted exercises were performed, then assisted active motion was

done with no limitation of the range of motion (ROM) for 4 to 6 weeks.

Group II

The patients in Group II underwent extracorporeal shock wave therapy. Group II consisted of 50 patients (28 women, 22 men), with a mean age of 49.6 ± 7.5 years (range, 31–63 years) and a mean duration of pain of 52.6 ± 54.4 months (range, 12–66 months; mean 38.5 months). There were 28 Type I deposits and 22 Type II deposits according to the Gartner¹³ classification. The right shoulder was affected in 56% of the patients.

High-energy extracorporeal shock wave therapy was performed by an experimental device (Siemens AG, Erlangen, Germany), characterized by the integration of an electromagnetic shock

wave generator in a mobile fluoroscopy unit. Once the calcium deposit was situated in the center of the C-arm, the shock wave unit was docked to the shoulder by means of a water-filled cylinder. Common ultrasound gel (University Hospital Mainz, Mainz, Germany) was used as a contact medium between cylinder and skin. Three thousand impulses of 0.60 mJ/mm² were administered with the patient under regional anesthesia. Only one therapy session was undertaken with each patient. No cold therapy or nonsteroidal antiinflammatory drugs were allowed after the procedure. Active exercises began as an outpatient treatment the day after shock wave therapy for 4 to 6 weeks.

Method of Evaluation

Followup evaluations were done independent of the treating orthopaedic surgeon at 12 months and at 24 months. The University of California Los Angeles rating for pain and function of the shoulder as reported by Kay and Amstutz²² was used to grade each patient before treatment and at each followup. According to this schema, pain and function are rated on a scale of 1 to 10 points, with 1 point being the worst score and 10 points being the best score. The range of active forward flexion and strength in forward flexion were scored from 0 to 5 points; and the satisfaction of the patients was scored from 0 to 5 points. The maximum score to be achieved was 35 points. The outcome score was as follows: more than 33 points, excellent; 29 to 33 points, good; and less than 29 points, poor.

Radiologic Evaluation

An AP view,²³ and an outlet view of the acromion were obtained 1 day before surgery or extracorporeal shock wave therapy, and at 12 months after either treatment. On the AP views, resorption was graded as none, partial, or complete by the authors' colleagues from the local Department of Radiology who were blinded to the treatment status and antecedent studies.

Statistics

Statistical analysis was done by the local Institute of Medical Statistics and Documentation. Differences between the groups regarding pain, function, flexion, strength, and total outcome were tested by using Wilcoxon's test for two independent samples. Fisher's exact test for 2 × 2 contingency tables was used for the analysis of satisfaction and outcome, and its extended version was used to test the removal of

the calcific deposits and the time until the patients returned to work. The comparison of preoperative data with data from the 12-months, and 24-months followups was done by Wilcoxon's signed rank test for pain, function, flexion, strength, and total outcome. Differences in time concerning the patients' satisfaction and the outcome were done by McNemar's test. Dependencies between removal of the deposit, return to work, and outcome were tested with Fisher's test and its extension. Differences in total outcome scores according to different radiologic outcome and removal of the deposits were shown with Wilcoxon's test. The level of significance alpha was set to 5% for each test; therefore p values less than 0.05 were considered significant. All tests were calculated two-sided; multiple adjustment was not done.

RESULTS

Rate of Followup

At 12 months, 20 patients in Group I and 45 patients in Group II were examined. At 24 months, 20 patients in Group I, and 39 patients in Group II were examined. The remaining patients were lost to followup. Regarding the epidemiologic data, the patients who were lost to followup did not differ from the patients included in the current study.

Clinical Outcome in the University of California Los Angeles Score

The total outcome in the University of California Los Angeles Score is shown in Table 2 and in Table 3. The comparison of both groups regarding point values or regarding excellent and good outcomes showed no significant difference at 12 months. At 24 months, point values were significantly higher in Group I than in Group II (32.4 points versus 29.1 points; $p < 0.001$), and there were significantly more excellent and good results in Group I than in Group II (90% versus 64%; $p < 0.05$).

Radiologic Outcome

The extent of elimination of the calcium related to its radiomorphologic features is shown in Table 4.

Group I: At 12 months, the calcium deposit had disappeared in 85% of the patients; in 15%

TABLE 2. Points According to the University of California Los Angeles Rating System

Followup (months)	Group I			Group II			p Value		
	Total	Gärtner I	Gärtner II	Total	Gärtner I	Gärtner II	Total	Gärtner I	Gärtner II
	0	17.8 ± 4.0	18.0 ± 3.4	17.4 ± 4.7	19.0 ± 3.3	18.7 ± 3.2	19.2 ± 4.8	NS	NS
12	30.3 ± 3.2	29.3 ± 3.8	31.7 ± 4.5	28.3 ± 6.9	26.7 ± 3.6	30.6 ± 4.3	NS	<.01	NS
24	32.4 ± 2.9	32.0 ± 4.1	33.1 ± 3.9	29.1 ± 4.2	26.7 ± 3.6	31.9 ± 4.7	<.001	<.0001	NS

mean ± standard deviation; NS = not significant.

TABLE 3. Outcomes According to the University of California Los Angeles Rating System

Followup (months)	Group I						Group II						p Value					
	Total		Gärtner I		Gärtner II		Total		Gärtner I		Gärtner II		Total	Gärtner I	Gärtner II			
	E	P	E	P	E	P	E	G	P	E	G	P	E	G	P			
0	—	100	—	100	—	100	—	100	—	100	—	100	NS	NS	NS			
12	50	25	42	33	25	63	12	25	40	20	40	28	20	52	55	20	25	
24	55	35	10	50	42	8	63	25	12	46	18	36	43	10	47	56	28	16

E = excellent; G = good; P = poor; NS = not significant.

Numbers given are percent of patients.

TABLE 4. Elimination Rates of the Calcific Deposits at 12-month Followup

Elimination of Deposit	Group I		Group II	
	Gärtner I n = 12	Gärtner II n = 8	Gärtner I n = 25	Gärtner II n = 20
Complete	84%	88%	28%	70%
Partial	16%	12%	36%	30%
None	—	—	36%	—

of the patients, only minor particles were observed. There was no significant difference regarding the radiomorphologic features.

Group II: At 12 months, complete resorption was observed in 47% of the patients (Figs 2, 3) and partial resorption of the calcium deposit was observed in 33% of the patients. In 20% of the patients, there was no change of the morphologic features.

The calcium deposit was no longer detectable radiologically in significantly more patients in Group I than in Group II ($p < 0.0001$). Complete disintegration of the calcium was found significantly more often in patients with Gärtner II deposits than in patients with Gärtner I deposits (70% versus 28%; $p < 0.0001$).

Radiologic Morphologic Features and Clinical Outcome

In Group I, patients with Gärtner Type I deposits had 29.3 points at 1 year and 32 points at 2 years; patients with Gärtner Type II deposits had 31.7 points at 1 year and 33.1 points at 2 years.

In Group II, patients with Gärtner Type I deposits had 26.7 points at 1 year and at 2 years; patients with Gärtner Type II deposits had 30.6 points at 1 year and 31.9 points at 2 years.

Patients in Group I with Gärtner Type I deposits had significantly better point values according to the University of California Los Angeles score than patients in Group II at both followups (all $p < 0.0001$). There was no significant difference between patients in Group I and Group II who had Gärtner Type II deposits (Table 3).

In Group I, 75% of patients with a Gärtner Type I deposit had excellent or good outcomes at 1 year, and 92% had excellent or good outcomes at 2 years. Seventy-five percent of patients with a Gärtner II deposit had excellent or good results at 1 year, and 88% had excellent or good results at 2 years.

In Group II, 48% of the patients with a Gärtner I deposit had excellent or good out-

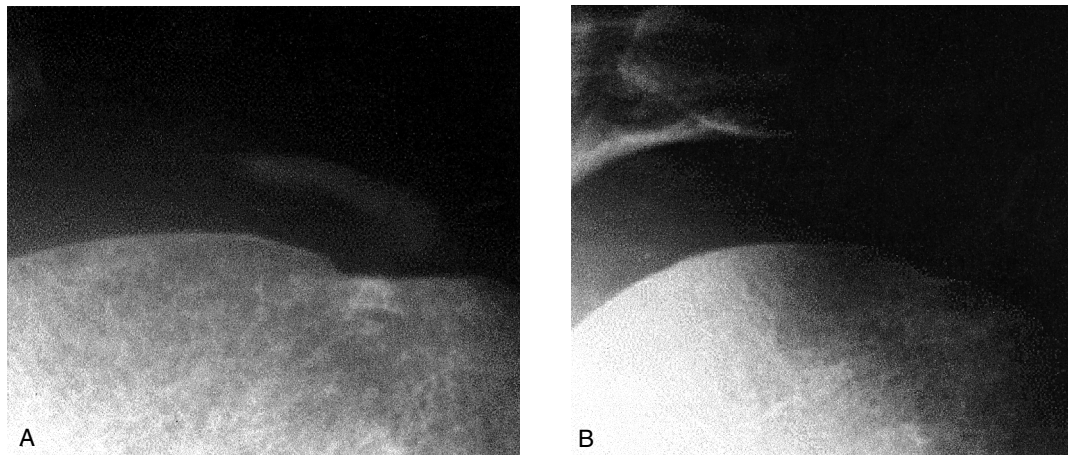


Fig 2A–B. (A) Anteroposterior radiograph showing a Gärtner I calcium deposit (homogenous structure with well defined borders). (B) Anteroposterior radiograph showing complete disintegration 12 months after shock wave application.

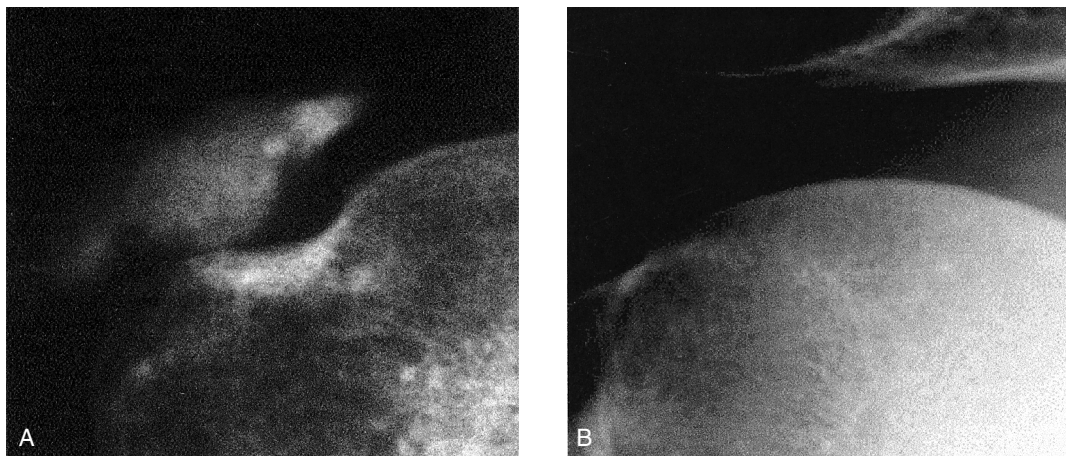


Fig 3A–B. (A) Anteroposterior radiograph showing a Gärtner II deposit (inhomogenous structure with well defined border). (B) Anteroposterior radiograph showing a complete disintegration 12 months after shock wave application.

comes at 1 year, and 53% had excellent or good results at 2 years. Seventy-five percent of patients with a Gärtner II deposit had excellent or good outcomes at 1 year, and 84% had excellent or good outcomes at 2 years. At both followups there were significantly more excellent or good outcomes in patients in Group I with Gärtner Type I deposits than in Group II (12 months, $p < 0.01$; 24 months, $p < 0.0001$). There was no significant difference between patients in Group I and Group II who had Gärtner Type II deposits (Table 4).

Hospital Stay

Patients in Group I remained in the hospital for an average of 12 ± 4.5 days and patients in Group II remained in the hospital for 3.1 ± 0.65 days. The period of hospitalization was significantly shorter for patients in Group II ($p < 0.0001$), which means an average cost advantage of \$2970 per patient in Group II.

Absence from Work

After being discharged from the hospital, patients in Group I returned to work an average of 9.1 ± 11.6 weeks, and patients in Group II returned to work an average of 2.5 ± 3.0 weeks. Absence from work was significantly

shorter for patients in Group II ($p < 0.01$), which means an average cost advantage of \$9240 per patient in Group II.

Complications

Although one deep wound infection was observed in a patient from Group I, no side effects except for transient subcutaneous hematoma were observed in patients from Group II (Fig 4). Lesions in the rotator cuff were ruled out by MRI or through ultrasonography after shock wave therapy.

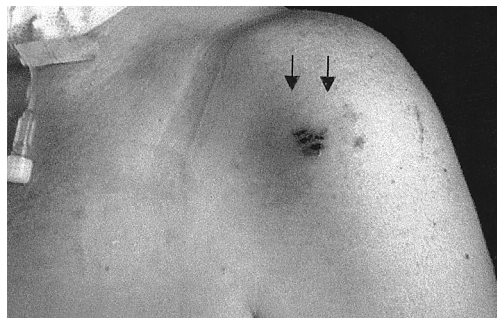


Fig 4. A hematoma after high-energy extracorporeal shock wave therapy in the contact area of shock wave device and skin is shown.

Subjective Rating

At 24 months, 55% of the patients in Group I reported complete relief of pain, and 29% had significant reduction of pain. Five percent and 11% of the patients observed only slight or no improvement, respectively.

In Group II, 43% of patients did not have pain and 24% had a significant reduction of pain. Four percent and 29% of the patients had a slight relief or no reduction of pain, respectively. With the numbers available, a significant difference between Group I and Group II could not be detected.

DISCUSSION

The usual conservative treatment for patients with the chronic or subacute phase of calcifying tendinitis comprises physical therapy, infiltration with local anesthetics or corticosteroids or both, and needling and lavage. The reported success rates vary between 30% and 85%.^{8,13,18,25,33,36,39,53} In a series of 100 patients treated conservatively Litchman et al²⁶ reported only one patient who had to undergo surgery. The effect of ultrasonic energy is questionable.¹⁵ Radiation therapy is not an acceptable mode of treatment according to the studies of Chapman,⁵ Young,⁵⁴ and Plenk.³⁷

Open surgery is regarded as a dependable and quick method to relieve the deposit. Verbostad⁵¹ reported excellent and good results in 34 of 43 patients (79%), and Gschwend et al¹⁶ reported excellent and good results in 25 of 28 patients (89%). Rubenthaler and Wittenberg⁴⁴ observed 88% excellent and good results. Rochwerger et al,⁴⁰ also using the open procedure, reported an increase of the Constant score values from 52 points to 89 points after a followup of 23 months.

The endeavour to avoid damage to the deltoid muscle led to the development of minimally invasive techniques, guided by arthroscopy.^{10-12,14} In prospective studies, this technically demanding procedure has proven to be successful.^{1,2,10,17,39,45} Ark et al² observed 50% excellent results. Molé et al³⁰ reported that 82% of their patients were satisfied with postoperative

outcome. Similar to Jerosch et al²¹ and Re and Karzel,³⁸ the authors could not show an improvement of results with an associated acromioplasty. All authors with the exception of Tillander and Norlin⁴⁷ stressed the importance of complete removal of the calcific deposit; subacromial decompression was thought to be of minor importance.

In a preliminary study, Loew et al²⁸ discussed the potential disintegrating capability of extracorporeal shock waves regarding calcific deposits of the rotator cuff. They proposed that increasing pressure within the therapeutic focus caused fragmentation and cavitation effects inside the amorphous calcifications and led to disorganization and disintegration of the deposits. A breakthrough of the calcific masses into the adjacent subacromial bursa or local resorptive reaction of the surrounding tissue induced by extracorporeal shock waves possibly led to the disappearance of the deposits. The exact working mechanism remains unclear. In an in vitro study, Perlick et al³⁵ put artificial concretions in the rotator cuff of a pig, and reported that it took at least 2000 to 3000 impulses of an energy flux density of 0.42 mJ/mm² to achieve disintegration of the deposit.

Clinically, Loew et al²⁸ reported significant improvement of symptoms in 14 of 20 patients (70%) after two applications of 2000 shock waves of an energy flux density of 0.3 mJ/mm². Radiologically, there were seven cases of complete resorption and five cases of partial disintegration. However, the followup was only 12 weeks. Radiologically, these results were much better than the data reported in the authors' first preliminary series⁴¹ in which complete elimination of the deposit was observed in only 15% of 40 patients who were treated once with 1500 impulses of an energy flux density of 0.28 mJ/mm². Daেকে et al⁷ showed an influence of two applications versus one application of 2000 shock wave impulses of an energy flux density of 0.3 mJ/mm² in 115 patients. On radiographs, complete elimination of the deposit was seen in 54% of patients (two treatments) and in 33% of pa-

tients (one treatment) and partial disintegration was seen in 23% of patients (one treatment) and 14% of patients (two treatments). The differences in the radiologic findings were significant in favor of two applications. Clinically, 54% of patients versus 45% of patients did not have pain after 6 months, and 75% of patients versus 65% of patients attained at least 75% of the age- and gender-dependent values of the score of Constant and Murley.⁶ However, the differences of both treatment groups were not statistically significant. Krischek et al²⁴ observed 50 patients for 1 year after one application of 3000 shock waves of an energy flux density of 0.28 mJ/mm². Thirty-four percent of the patients were satisfied and 18% of patients were moderately satisfied. Radiologically, deposits had been eliminated completely in eight patients, whereas 21 patients had partial disintegration. According to the Gärtner¹³ classification, they observed changes of the radiologic morphologic features in 88% of Grade II deposits, but in only 44% in Grade I deposits. Clinically the Constant and Murley score⁶ values improved from 60 to 76 points. Therefore, by doubling the number of applied shock waves compared with previous studies, neither an increase of the elimination rate nor an improvement of the clinical outcome was achieved. Eighteen of 50 patients (36%) had to be operated on for persistent symptoms. Spindler et al⁴⁶ reported three patients to be asymptomatic 2 years after one shock wave application. Recently Loew et al²⁷ included 195 patients in their prospective investigation and reported subjective recovery in 58% of patients and complete or partial disintegration of the deposits in 72% of patients at 6 months after two sessions of high-energy shock wave application.

The reports from Daecke et al⁷ and Krischek et al²⁴ indicated that there was a correlation between radiologic morphologic features of the deposit, of the amount of total energy applied, and of the rate of disintegration.

To increase elimination of the deposit in the patients of the current study, the energy flux density was doubled to 0.6 mJ/mm², promot-

ing complete disintegration to 70% in Gärtner Type II deposits and 28% in Gärtner Type I deposits compared with an overall 15% in an earlier study.⁴¹ Despite the use of shock waves of such a high-energy flux density, not one case of damage to the rotator cuff, cartilage, and bone was observed on radiographs, ultrasonographs, or MRI scans.

The results of the current study once again show the importance of complete removal of the calcium. The finding of an association of complete disintegration of the deposit and good outcome⁴² supports similar observations published recently by Perlick et al.³⁵ They treated two groups of patients two times with 2000 impulses of an energy flux density of 0.23 mJ/mm² or 0.42 mJ/mm². Regarding the radiologic appearance of the deposits, they described an improvement of the values of the Constant and Murley score⁶ from 53.6 to 80.2 points after complete elimination of the calcium, compared with an improvement from 51.7 points to 61.4 points only when the deposit remained unchanged.

Keeping in mind that conventional nonoperative procedures had failed in all of the patients, a success rate of 64% after 2 years, the longest followup reported after high-energy shock wave therapy for calcifying tendinitis to date, seems to be satisfying. However, compared with surgery, the success of resolution of the deposit was worse. Clinically, despite large differences in the elimination of the calcareous deposits in favor of the surgery (85% versus 47%), there were only small, although statistically significant differences in the University of California Los Angeles rating system after 12 months (30.3 versus 28.3 points), and after 2 years (32.4 versus 29.1 points). However, the length of hospital stay was four times longer after open surgery compared with after shock wave therapy (12 days versus 3 days). Regarding endoscopic procedures, this difference is expected to be only marginal. Patients who had surgery returned to work after an average of 9 weeks and patients who were treated with shock waves returned to work after an average of 2 weeks.

Surgical extirpation of a calcific deposit still is the gold standard in the treatment of patients with chronic calcifying tendonitis if neither anatomic outlet impingement nor functional impingement has been found on radiographs and MRI scans. This surgical procedure proved to be superior to the high-energy shock wave modalities chosen in the current study, in the University of California Los Angeles rating system and radiologically, when the calcium deposit was of homogenous structure and sharply outlined (Gärtner Type I deposit). However, in patients with deposits of inhomogenous structure with a sharp outline or in patients with deposits of homogenous structure but with no defined outline (Gärtner Type II deposit), there was no clinical advantage of surgery compared with high-energy shock wave therapy. On the contrary, surgery led to extra costs of more than \$12,000 until the patient returned to work. The current authors agree with Loew et al²⁷ that shock wave therapy is effective for patients with chronic calcifying tendinitis of the shoulder.

Originally, a prospective randomized pilot study was planned to compare operative outcomes and results after extracorporeal shock wave therapy for calcifying tendonitis. The local ethical committee already had agreed to a pilot study. However, the majority of the patients denied consent to being randomized to a surgical procedure, as long as there still was the possibility of being treated nonoperatively with shock waves. The authors, therefore, had to stop the prospective randomized study. Selection and information bias cannot be ruled out in the current study. Additional randomized and controlled studies are mandatory to establish the optimum treatment regime with extracorporeal shock wave therapy for patients with a recalcitrant calcific deposit of the rotator cuff, and to clarify which role removal of the deposit or subacromial decompression or both play in surgical treatment.

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