

Efficacy of extracorporeal shock-wave treatment for calcific tendinitis of the shoulder: experimental and clinical results

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Abstract The effects of various extracorporeal shock wave energy levels and impulse rates were investigated using an *in vitro* model. In addition, we performed a controlled, randomized study to examine the clinical outcome after treatment for calcific tendinitis of the shoulder. Two groups of 40 patients each received 2000 impulses twice with an energy flux density of 0.23 mJ/mm² and then 0.42 mJ/mm². The results were evaluated by the Constant and Murley score. Disintegration of the implanted deposits requires an energy of at least 0.42 mJ/mm² and 2000 impulses. The clinical trial showed resorption of calcific deposits in 37.5% (0.23 mJ/mm²) and 55.0% (0.42 mJ/mm²). After 1 year the Constant and Murley score increased from 46 to 68 at 0.23 mJ/mm² and from 48 to 73 points at 0.42 mJ/mm². Based on our experimental and clinical results it is evident that disintegration of calcific deposits is dose-dependent. Because of the time that elapses until changes became evident on the radiographs, an instant and sole mechanical effect on the calcific deposits is unlikely. Therefore, a combined mechanical and cellular mechanism for absorption of the calcific deposits must be presumed.

Key words Calcific tendinitis · Shock wave · Lithotripsy · Shoulder · Rotator cuff

Introduction

The first reports of calcific tendinitis of the rotator cuff date back over a hundred years, and even then these changes were thought to be one of the main causes of non-traumatic stiffness and pain of the shoulder. Calcific tendinitis can be subdivided into cell transformation, calcification, resorption, and finally reparation. Independent of this progression, the periarticular calcified deposits were found to be poorly mineralized hydroxyapatite.³ The exact etiology and pathomechanism

of chronic calcifying tendinitis currently remain unresolved, and theories concerning a mechanical, vascular, or biochemical genesis are to a great degree speculative. In only a few cases have radiographs of asymptomatic shoulders shown periarticular calcification mostly localized in the supraspinatus tendon. As yet, there are no accepted criteria for predicting the progress of the disease¹³; and although a correlation between the size of deposits and the frequency of complaints has been described, morphological findings and severity of symptoms frequently show a marked discrepancy.

Although the disease is in some case self-limiting without specific therapy — spontaneous disappearance of periarticular calcifications was reported in 9.3% after 3 years and 27% after 10 years — frequently surgical treatment remains the last resort in chronic cases with pain-induced successive restriction of shoulder mobility. As an alternative, minimally invasive extracorporeal shock wave therapy (ESWT) has been postulated to be an effective tool for treating calcific tendinitis of the shoulder.^{9,13} Medium- and high-energy shock waves are expected to exert a direct, mechanically disintegrating effect on hard surfaces such as calcareous deposits in the supraspinatus tendon; low-energy shock waves are used as a form of hyperstimulation analgesia.

In a combined initial *in vitro* study followed by clinical trials we aimed to verify the efficacy of ESWT in the treatment of calcific tendinitis of the rotator cuff and to determine if there is an energy dependence in the clinical outcome. Furthermore, different modalities of shock-wave application were analyzed and are discussed concerning their clinical value.

Materials and methods

In vitro study

A special technique⁴ was used to produce biometric artificial stones. Standard artificial carbonate apatite



Fig. 1. Forelimb of a 12-month-old house pig placed on the Lithostar Lithotripter during X-ray control

stones were produced by the Department of Experimental Urology, University of Bonn, Germany by a coating technique where several layers of a suspension are applied around a core. The artificial stones [Bon(n) stones] fulfill all norms for a standard stone model and are suitable for use in systemic scientific investigations on disintegration.

As calcific tendinitis has not yet been described in mammals other than humans, we simulated the morphological condition by implanting these Bon(n) stones into the shoulder girdle muscles of sixteen 12-month-old pig's shoulders. To imitate an *in vivo* situation the stones were implanted covered by a thin rubber condom filled with 2 ml of ethanol to simulate a fluid mantle.¹⁷ The implantation of stones into the pig shoulders was performed following a standardized procedure of radiographic localization of the humerus and paracentesis. After implantation the pig's shoulders were placed on the Siemens Lithostar Lithotripter (Fig. 1), control radiographs were obtained, and then treatment with 2000 shock waves (100/min) with an energy flux density (EFD) of either 0.23, 0.33, 0.42, or 0.54 mJ/mm was carried out in four shoulders each.

Afterward the condoms with the now disintegrated Bon(n) stones were extracted and the stone fragments

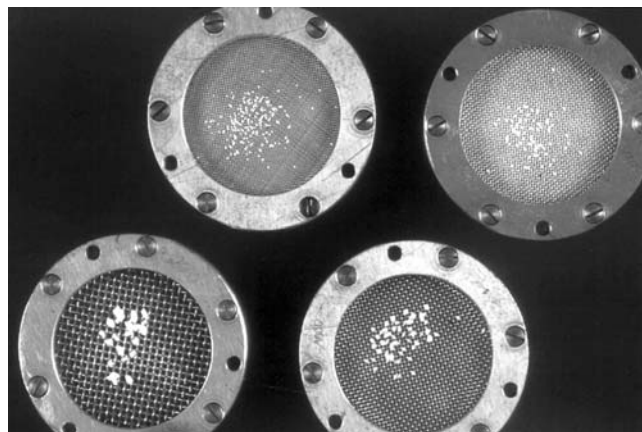


Fig. 2. Fragments won in four sieves of the sieving cascade after application of 2000 shock waves with an energy flux density (EFD) of 0.54 mJ/mm²

collected in a Petry cup. After desiccating the fragments, they were separated according to size using a sieving cascade (Fig. 2) constructed by the Department of Experimental Urology, University of Bonn. By this method 13 particle fractions of 2000, 1400, 1000, 710, 500, 355, 250, 180, 125, 90, 63, 45, and 25 μ m were obtained. We then weighed the individual fractions.

Clinical study

From 1995 to 1998 a total of 80 patients were included in this clinical trial: 36 men and 44 women with a mean age of 48.4 years (range 38–64 years). The patients were randomly assigned in blinded fashion to two groups. The mean duration of symptoms was 32 months. All patients consented to enter the study after a detailed explanation of the techniques, the possible risks of shock-wave treatment, and the alternative nonoperative and operative management options.

Only patients were included who had had shoulder pain for at least 12 months that had been resistant to regular physiotherapy and subacromial injections of steroids. Furthermore, an area of radiological calcification at least 1 cm in diameter with no signs of disintegration or type I or II resorption according to the classification of Gärtner and Heyer³ was required. Patients with cloudy and transparent calcifications (type III) were excluded. Rotator cuff lesions were excluded by means of sonography and in some cases by magnetic resonance imaging (MRI). Additional reasons for exclusion were evidence of subacromial impingement of the rotator cuff independent of the calcareous deposits, dysfunction in the cervical spine, generalized polyarthrititis, pregnancy, infection, or a record of tumor disease.

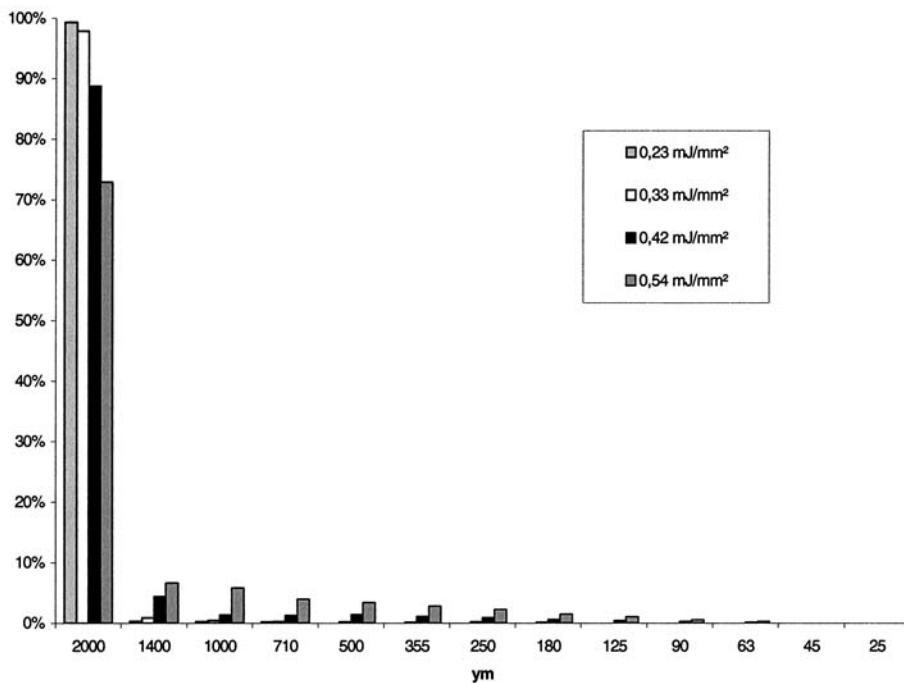


Fig. 3. Fragmentation of the implanted stones by using an EFD of 0.23, 0.34, 0.42, or 0.54 mJ/mm² ($n = 20$)

Group 1 received 2000 impulses (EFD 0.23 mJ/mm²) in two sessions with an interval of 3 weeks between treatments. Group 2 was treated with an EFD of 0.42 mJ/mm² in two sessions with 2000 shock waves (100/min), also with an interval of 3 weeks. The Siemens Lithostar-Lithotripter was used in both groups. Function of the treated shoulder was evaluated by comparing the Constant and Murley score before as well as 3 and 12 months after shock-wave treatment.

All treatments were performed as outpatient procedures after subcutaneous infiltration of local anesthetic (10 ml bupivacaine hydrochloride 0.5%). The calcific deposits were visualized using the inline sector scanner prior to treatment. Shock-wave application was started with a low EFD that was increased to the planned energy level within the first 300 shock waves. Most patients found the treatment unpleasant and in some cases painful.

Statistical methods

The radiographs and clinical scores were interpreted and the measurements taken solely by two of the authors (L.P. and O.D.). Statistical analysis was performed using the paired *t*-test and one-way analysis of variance (ANOVA). The paired Student's *t*-test was used to analyze the differences in the clinical data between the two groups. A *P* value of less than 0.05 was considered significant and *P* values of less than 0.01 as highly significant.

Results

Experimental results

The application of 2000 impulses of 0.23 mJ/mm² showed almost no effect on the implanted artificial stones. Treatment of the limb at this EFD level led to only a few medium-sized fragments (Fig. 3). The increase of the EFD to 0.33 mJ/mm² did not significantly increase fragmenting effects of the shock waves on the stones. Only 3% of the total weight was found to be fragmented, the smallest fragment reaching the size of 180 µm. An EFD of 0.42 mJ/mm led to slight increase in fragmentation, with the weight of the fragmented particles being 12% of the total weight, and the size of the fragments going down to 63 µm. An EFD of 0.54 mJ/mm led to an increase in the fragments to 27% of the total weight with a relatively larger proportion of small fragments.

Clinical results

Radiographic outcome

Radiographs obtained 1 year after shock-wave treatment (Fig. 4) showed no change in the calcium deposits in 25 patients (62.5%) of group 1 (0.23 mJ/mm²) and in 18 patients (45.0%) of group 2 (0.42 mJ/mm²). Partial resorption was observed in 9 patients (22.5%) in group 1 and 8 patients (20.0%) in group 2. An increase of the EFD (0.42 mJ/mm²) led to a higher incidence of total

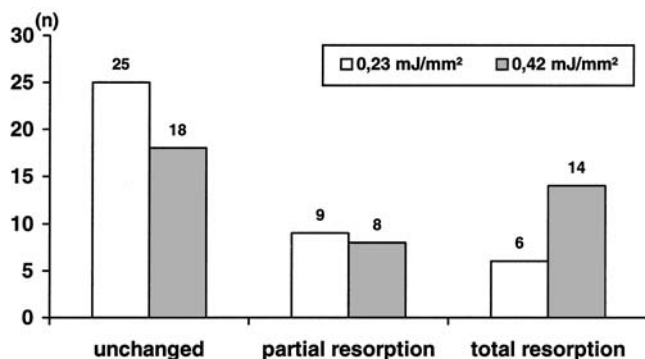


Fig. 4. Radiographic changes of the calcific deposits over a period of 1 year ($n = 80$)

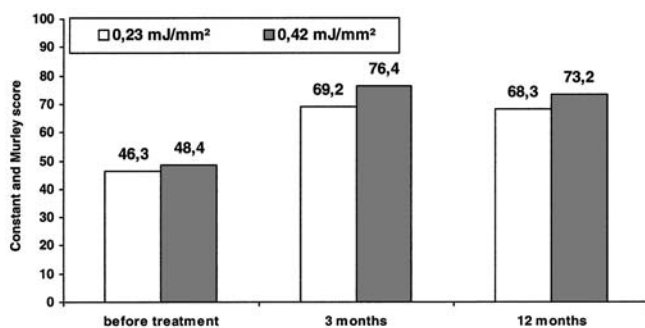


Fig. 5. Changes in the Constant and Murley score over a period of 1 year after shock-wave treatment. The differences between group 1 (0.23 mJ/mm²) and group 2 (0.42 mJ/mm²) are not significant ($P > 0.05$)

resorption of the calcium deposits, though these differences were not found to be significant. Complete resorption was evident in 6 patients (15.0%) of group 1 and 14 patients (35.0%) of group 2.

Constant and Murley score

The mean total shoulder function (Fig. 5) for patients in group 1 (0.23 mJ/mm²) was 46.3 points before the start of ESWT. Twelve weeks later there was a significant mean increase to 69.2 points. One year after shock-wave treatment a slight decrease to 68.3 points ($P < 0.01$) was observed. The mean total shoulder function for patients in group 2 was 48.4 points (range 22–81 points) prior to the initial shock-wave treatment. Twelve weeks later there was a mean increase of 32% to 76.4 ($P < 0.01$). After 1 year once again a slight decrease to 73.2 points ($P < 0.01$) was found. The 12-month follow-up showed a tendency toward better results in group 2 (0.42 mJ/mm²) without a statistical difference ($P = 0.13$).

Focusing on the development of the subscore for pain, we found an increase from 3.2 to 9.0 in group 1 (0.23 mJ/mm²) after 12 months and from 4.2 to 10.5 in group 2 (0.42 mJ/mm²). Range of motion showed an increase from 18.2 to 26.8 in group 1 (0.23 mJ/mm²) after 12 months and from 19.5 to 29.3 in group 2 (0.42 mJ/mm²) (Tables 1, 2).

Comment

The decrease in the Constant and Murley score correlated well with an increase of subjectively described pain in the group of patients who showed no radio-

Table 1. Development of the pain subscore (modified as a visual analogue scale) of the Constant and Murley score in the two groups ($n = 40$)

Group	Pain (max. 15, VAS)		
	Before treatment	3 Months after treatment	12 Months after treatment
EFD 0.23 mJ/mm ²	3.2 ± 2.7	9.8 ± 3.1	9.0 ± 3.7
EFD 0.42 mJ/mm ²	4.2 ± 2.5	11.2 ± 3.4	10.5 ± 3.2

EFD, energy flux density; max., maximum; VAS, Visual Analogue Scale

Table 2. Development of the range of motion subscore of the Constant and Murley score in the two groups ($n = 40$)

Group	ROM (max. 40)		
	Before treatment	3 Months after treatment	12 Months after treatment
EFD 0.23 mJ/mm ²	18.2 ± 7.4	28.2 ± 8.5	26.8 ± 9.2
EFD 0.42 mJ/mm ²	19.5 ± 6.6	31.1 ± 8.4	29.3 ± 8.6

Rom, range of motion

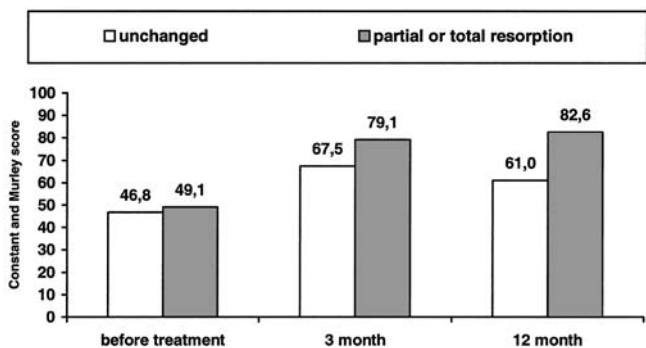


Fig. 6. Changes in the Constant and Murley score in patients with and without radiographically evident changes of the calcific deposits ($n = 80$)

graphic change in their calcium deposits. In parallel to the persisting radiographically evident calcified deposits at the 1-year follow-up, there was only a slight increase in the Constant and Murley score, from 46.8 to 61.0 points (Fig. 6). In contrast, patients with radiographically verified partial or complete resorption of the calcified deposits showed an increase in the mean Constant and Murley score from 49.1 to 82.6 points. The results were highly significant, with $P < 0.01$.

Complications

In both groups complications were observed only in the form of hematomas. Fifteen patients in group 1 and all patients of group 2 showed mild local intracutaneous, petechial bleeding. A superficial hematoma was found in one patient of group 1 and eight patients of group 2. Two patients of group 1 and three patients of group 2 developed acute pain in the treated shoulder immediately after shock-wave therapy, making an oral analgesic necessary. Some patients returned to our clinic earlier than the 3-month examination because of acute shoulder pain. Within the clinical routine only these patients were examined by ultrasonography. We found sonographic signs of acute bursitis subacromialis in two patients of group 1 and four patients of group 2, possibly associated with shock-wave-induced penetration of the calcium deposits into the adjacent subacromial bursa. All these patients showed complete resorption of the calcified deposits at further follow-up visits and significant clinical improvement.

Discussion

The causal relation between calcareous deposits in a rotator cuff tendon and shoulder pain or stiffness is not always obvious, making calcific tendinitis a difficult entity to diagnose and treat. The cause and the course of this self-limiting disease are to a great extent unknown,

and the theories postulated remain controversial.¹³ Frequently, initial treatment modalities for the disease are aimed primarily at symptoms, focusing on adequate analgesia with nonsteroidal antiinflammatory drugs (NSAIDs) or local infiltration of crystalline steroidal suspensions, biding time until the symptoms are alleviated. Only in resistant cases are further, more invasive steps considered, with surgery being the ultimate step.

ESWT presents a noninvasive treatment for chronic calcific tendinitis of the shoulder. The basic idea is to provide local analgesia by low-dose shock-wave generated hyperstimulation and to induce resorptive and reparative processes by applying medium energy density.¹² Since 1992, ESWT has been used in Germany and Austria to treat calcifying tendinopathy of the shoulder. The number of applications in the orthopedic area, with an estimated 60 000–100 000 patients annually in Germany, has exceeded the number of applications of lithotripsy in urology. Clinical success is reported in 60%–80% of patients from uncontrolled prospective trials.^{4,10,11,15}

Currently, the exact mechanisms of the therapeutic effects of shock-wave therapy on shoulder calcification remain uncertain. The hypothesis is that increasing pressure within the therapeutic focus causes fragmentation and cavitation inside the amorphous calcifications, leading to disorganization and disintegration of the deposits. Disappearance of the deposits may be due either to breakthrough into the adjacent subacromial bursa or local resorptive reactions in the surrounding soft tissues.⁹

Our experimental results tend to confirm the hypothesis that resorption of the calcific deposits is normally induced by a cellular mechanism and not through direct physical disintegration.²⁰ To bring about microtrauma by means of shock waves, it is necessary to have discrepancies in impedance between two soft-tissue layers, thereby permitting energy transfer. This is the case where calcific deposits have a high degree of crystallized hydroxyapatite, making them fairly solid and resulting in significant differences in impedance to surrounding soft tissue. It is more difficult to evaluate the effects of shock waves in cases where the surrounding soft tissue and the calcific deposits have similar densities; that is, the calcific deposit is relatively liquid. Here the energy transfer may not be sufficient to cause adequate mechanical disintegration of the deposit. This phenomenon may be the reason for the clinically observed nonresponders despite a theoretically sufficient EFD. As the structure of the calcific deposit cannot be adequately assessed by means of conventional radiography, sonography, or computed tomography (CT) scans, selection of patients who may have greater benefit from this mode of treatment is impeded.¹² As discussed, though not a proven indicator, MRI may reveal associ-

ated perifocal edema in the vicinity of the deposit, indicating that there is insufficient discrepancy in impedance.

Although our experimental results suggest a mechanical effect of shock waves on calcific deposits, the theory of a shock-wave-induced cellular mechanism playing a significant role in reparative processes cannot be dismissed. It has been shown that mechanical irritation can effectively activate an inflammatory response on a microvascular level, with leukocyte recruitment, extravasation, and chemotaxis. Despite the fact that little is known about the effects of shock waves on the microcirculation of striated muscle, reason makes it seem possible that the cavitation effect, which is able to cause lesions of cell membranes¹⁴ (0.12 mJ/mm^2) and nuclear membranes (0.50 mJ/mm^2), may induce local mechanical soft-tissue irritation, leading to an adequate local inflammatory response. This remains hypothetical; and though further experimental studies are necessary to quantify the influence of the cellular and mechanical mechanisms, we believe that both play a significant role in resorptive and reparative processes.

In a controlled prospective randomized study, Haake et al.⁴ analyzed the effect of ESWT on calcifying tendinopathy of the shoulder focused on either the calcified area or the origin of the supraspinatus tendon. They showed statistically significant superiority of shock wave application at the calcified area in the primary endpoint. They therefore recommended exact fluoroscopic focusing of ESWT at the calcific deposit for treatment of calcifying tendinopathy of the supraspinatus muscle.

In another controlled, randomized study Schmitt et al.¹⁸ evaluated the effects of low-energy shock-wave therapy by comparing 20 patients treated with an energy flux density of 0.11 mJ/mm^2 with a control group who underwent sham ESWT after local anesthesia. They found no difference in the Constant and Murley score or pain and therefore did not recommend low-energy ESWT for therapy. This underlines our thoughts and the results of dose dependence of ESWT. Our experimental and clinical results demonstrate it clearly. We found that radiographically evident changes were verified in 37.5% (0.23 mJ/mm^2) and 55% (0.42 mJ/mm^2), respectively. This is comparable to the clinical results of Buch et al.,¹ who found either partial or total resorption of calcium deposits in only 13% (2/15) after low-energy ESWT at the 6-week follow-up and in 66% (10/15) after high-energy ESWT.

Analogous to our study, Rompe et al.¹² described a correlation between functional results and a reduction in deposit size in 75.0% of their patients. At the 12-month follow-up we again demonstrated a significant correlation between functional results and persisting calcific deposits. Patients in whom deposits had dimin-

ished or disappeared showed a notable improvement in the Constant and Murley score, emphasizing a connection between depot size and impairment of shoulder function.

The fact that positive clinical results are not inevitably combined with a radiographically evident resorption of the calcific deposit underline the fact that shock waves are well able to induce analgesia. Little is known about these effects; and in this study the observed analgesia, if not combined with verified morphological changes, frequently remained short-lived. This phenomenon has previously been described by Daecke et al.,² who reported a significant number of patients initially benefiting from shock-wave treatment despite no evident change in the deposits but again suffering from their original symptoms 6 months later.

The purpose of our incorporated clinical study was to try to bind an adequate treatment protocol. Because of the frequently observed self-limiting nature of calcific tendinitis of the shoulder, the use of ESWT is justified only in cases where the disease has gone into the phase of chronic calcification. We agree with previous authors^{8,13,21} that high-energy shock-wave therapy should be considered before surgery in patients with chronic calcific tendinitis after a minimum of 6 months of noninvasive treatment. Here ESWT should be reserved for Gärtner³ types I and II; type III is frequently associated with a high percentage of spontaneous remission. Based on the theory of Loew et al.⁸ concerning the size of a mechanically impeding calcific depot in the subacromial space, we believe that a verified deposit of a diameter of 10mm or more should be evident before ESWT is contemplated.

In contrast to the observation in surgically treated patients where clinical outcome improves further with time, we found a slight decrease of the Constant and Murley score. This could be due to a number of patients whose joint stiffness at the beginning of the trial did not improve after ESWT. Our data underline this point of view by the increased standard deviation for the range of motion in both groups. Nevertheless, the subscore for pain remained nearly constant between 3 and 12 months.

As suggested in previous studies and supported by our results, high-energy shock-wave treatment seems to be more efficient than low-energy treatment owing to the increased shattering effect on the deposit.^{13,21} An EFD of $0.20\text{--}0.30\text{ mJ/mm}^2$ seems advisable when the aim is fragmentation of a visualized calcific deposit (Fig. 4). Although this value is less than the EFOs in our in vitro and in vivo study that had a satisfactory shattering effect, side effects are kept to a minimum at this level and the pain induced is tolerable in most cases. The fact that the artificially implanted stone in our in vitro study is considerably harder than a typical calcific deposit

hinders direct transposition of the obtained results to the clinical situation.

We believe that two sessions with at least 1500 impulses each are necessary. Because of the high demands on staff and equipment, repeating the treatment until resorption of the calcific deposit is evident (as advised by Jakobeit et al.⁷) does not seem feasible from an economic point of view.

Although difficult to compare, the results of ESWT compare well with those derived from excellent follow-up studies of operatively treated patients with calcific tendinitis, as Rompe et al. showed in a recent comparative study.¹⁴ Rubenthaler and Wittenberg¹⁶ found 88.0% and Huber⁶ 92.1% of patients with good/excellent results after surgical management. Success rates of ESWT are significantly less than the before-mentioned results.

Nonetheless, taking into consideration that surgery is associated with a considerably higher risk and that the socioeconomic implications after surgical management are greater, ESWT certainly should be considered when treatment options for calcific tendinitis are contemplated. Possibly, the most efficient energy densities and optimal number of shock wave applications can be determined in further experimental and clinical studies to increase the efficacy of ESWT for chronic calcific periarthritis of joints.

Conclusions

Reviewing the literature and the results of our study indicate that ESWT has a therapeutic effect on tendinosis calcarea, as many authors have point out. Our experimental results showed the dose dependence of shock-wave treatment for disintegration of calcific deposits. Moreover, our clinical findings contribute to the hypothesis that a combined mechanical and cellular mechanism for absorption of the calcific deposits must be presumed because of the period of time until changes in the radiographs became evident. Therefore, an instant, sole mechanical effect on the calcific deposits is unlikely.

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