

## THE EFFECT OF EXTRACORPOREAL SHOCK WAVE THERAPY IN TREATMENT OF CALCIFYING TENDINITIS OF THE ROTATOR CUFF OF THE SHOULDER

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### Abstract

Calcifying tendinitis of a shoulder is a frequent disorder with an unknown etiology. It is usually treated with different physical therapy modalities where extracorporeal shockwave therapy comes as a new effective method.

Objective: to assess the impact of extracorporeal shockwave therapy in the treatment of calcifying tendinitis of the rotator cuff of the shoulder.

The study is a prospective, monocentric clinical study involving 13 patients who received extracorporeal shockwave therapy in 5 treatments, applied once a week in one session. The patients were evaluated with a Visual analog scale for pain and measurement of the range of motion of the shoulder joint. Clinical findings were evaluated before starting the treatment with extracorporeal shockwave therapy and at the end of the treatment, 5 weeks later.

After the treatment all the patients had statistically significantly better results in the Visual analogue scale for pain and the range of motion in the shoulder joint.

Extracorporeal shock wave therapy is a safe and non-invasive treatment that reduces pain and improves range of motion in the treatment of calcifying tendinitis of the rotator cuff.

**Keywords:** calcifying tendinitis, shoulder, extracorporeal shock wave therapy.

### Introduction

Calcifying tendinitis of the rotator cuff (CTRC) of the shoulder is a common disorder of unknown etiology. It is characterized by multifocal accumulation of calcium phosphate crystals within the tendons of the rotator cuff, leading to acute and chronic pain with limited range of motion and shoulder joint function.

The reported incidence of rotator cuff tendon calcifications varies from 2.7% to 20% of asymptomatic cases of CTRC of the shoulder [1]. It is estimated that 51% to 90% of calcifications are located at 1-2 cm. from the tendon insertion of m.supraspinatus. Women are more often affected than men, with studies finding that 57% to 76% of calcifying tendinitis occurs in female patients. The age distribution with the highest incidence was observed between the ages of 31 and 50, and there have been some reports of ethnic variations with an increased average age among Asians.

The origins of CTRC of the shoulder are still controversial. Several hypotheses have been proposed for the pathological process in CTRC: degenerative, recurrent trauma hypothesis, tenocyte necrosis, reactive, and endochondral ossification, but none of these explanations has been shown to be completely satisfactory.

The etiology of calcifying tendinitis of the rotator cuff is thought to be circulatory tissue hypoxia and localized pressure, which are the most common causative factors. Two fundamentally different processes have been proposed that lead to the formation of deposits of calcium: degenerative calcification and reactive calcification [2].

The pathogenetic mechanism of CTRC is still unclear. It appears to be associated with cell-mediated disease in which metaplastic transformation into chondrocytes causes calcification inside the tendon of the rotator cuff [3]. Calcium deposits consist of variable amounts of water hydroxyapatite crystals, carbonates and phosphates. The macroscopic appearance of calcifications changes from a granular conglomerate during the chronic or formative phase to the appearance of a milk emulsion in the acute or resorptive phase. The pathogenesis of CTRC can be divided into three phases, as reported

by Uhthoff et al [4]: precalcifying phase, with tendon transformation into fibrocartilaginous tissue which acts as a substrate for calcium deposition, then a calcifying phase, with true calcium deposition, consisting of a formative and resorption phase, and post-calcification phase, with remodeling of tendon tissue by fibroblasts around the calcium deposit, which can last for several months.

CTRC is most often presented with a persistent shoulder pain, functional disability, and the presence of calcifications of the symptomatic rotator cuff muscles. The clinical presentation of CTRC is very variable and depends on the stage which the patient is going through. The chronic formative phase can last from 1 to 6 years and can be completely asymptomatic. However, during the acute resorption phase, the patient usually has severe symptoms that can last from 3 weeks to 6 months. In general, the more severe the symptoms, the shorter the duration of the condition.

The diagnosis is made by using several methods. Conventional radiography can detect the presence of calcifications in the soft tissues around the humerus and in the subacromial space. Ultrasound diagnostics is a well-accepted modality for assessing soft tissue structures in the body. On ultrasound diagnosis, calcium deposits in the rotator cuff usually appear hyperechoic, with or without acoustic posterior shadow. Magnetic resonance imaging (MRI) is a well-established technique for imaging the musculoskeletal system, especially the shoulder. Although routine conventional shoulder radiography is sufficient to detect deposits, magnetic resonance imaging (MRI) provides a better evaluation of all coexisting pathology.

Treatment of calcifying tendinitis of the rotator cuff of the shoulder can be conservative and operative. Various modalities are used to treat this disorder, and most patients work well only with conservative treatment. Conservative treatment of CTRC usually includes initial "rest" and cryotherapy, oral administration of NSAIDs, massage to prepare the shoulder muscle groups for exercises, scapula mobilization, application of exercises starting with stretching exercises, continuing with ROM exercises, followed by resistance training for muscle strengthening, occupational therapy, kinesitherapy, electrotherapy, the use of therapeutic ultrasound, laser therapy, extracorporeal shock wave therapy, as well as the use of corticosteroid injections and PRP. Ogon et al. define failure of conservative treatment as persistence of clinical symptoms for at least 6 months, including 3 months of standardized treatment [5]. They conclude that the prognostic factors that significantly increase the possibility of failure of nonoperative treatment (negative prognostic factors) are bilateral calcifying deposits, localization on the anterior side of the acromion, and a large volume of calcifying deposit. Treatment can be modulated depending on the positive and negative prognostic factors.

The application of extracorporeal shock wave therapy (ESWT) is a newer conservative method for treatment of calcifying tendinitis of the rotator cuff of the shoulder. It is the application of the so-called shock waves who are vibrations of a sound wave that are generated and transported through tissue by interaction with fluid and solid particles. This creates local tissue injury, causing new growth of blood vessels, as well as an increase in the amount of tissue growth factors in the localized area.

### **Purpose**

The primary aim of this study was to evaluate the effect of extracorporeal shock wave therapy in the treatment of calcifying tendinitis of the rotator cuff of the shoulder. Secondary goals are to assess whether ESWT affects pain relief and whether ESWT improves range of motion in the shoulder joint in patients with calcifying tendinitis of the rotator cuff.

### **Material and method**

The study was a prospective, monocentric, controlled clinical trial involving 13 patients (between 36 and 71 years old) who received extracorporeal shock wave therapy. Patients were evaluated with the Visual Analogue Scale for pain and measurement of range of motion in the shoulder joint. Clinical findings were evaluated at the same time points for all patients, before the start of treatment with extracorporeal shock therapy and after 5 weeks, i.e. after the end of treatment.

The Visual Analogue Scale (VAS) for pain is consisted of a straight line with endpoints defining extreme boundaries, such as "no pain at all" and "very severe pain". The patient is asked to mark their level of pain on the line between the two end points. The distance between "no pain at all" and the patient's mark defines his pain.

The range of motion (ROM) of the shoulder joint is a very commonly used tool to assess the condition of this joint and its therapeutic effect. The measurement was performed using a universal goniometer.

Inclusion criteria for the selection of the candidates for this study were radiographically confirmed calcifying tendinitis of the rotator cuff of the shoulder followed by shoulder pain that persisted for more than 3 months and which did not diminish with other conservative treatment and aged 21 to 75 years. Exclusive criteria were inflammatory rheumatic disease, algodystrophic syndrome, pregnancy, infectious or malignant disease, partial or complete rupture of the rotator cuff muscle seen by echosonography, skeletal osteoporosis, skin ulcers and neurological disease.

Application of radial extracorporeal shock wave therapy was made with the Impactis M shockwave therapy unit (ASTAR Limited Liability Company, Poland). This device uses the pneumatic principle of shock wave generation.

During treatment there is constant contact of the tip of the applicator with the patient's skin. A total of 5 (five) treatments were applied, once a week, locally in the area of shoulder, according to the manufacturer's recommendations with continuous frequency, pressure 3.0 Bar, frequency 10 Hz, number of shocks 2000, duration of treatment - 7 minutes. For efficient transfer of shock waves as a contact medium between the skin and the radial probe, a gel was applied in the area of the shoulder joint.

Radial extracorporeal shock wave therapy was applied by positioning the patient in a comfortable upright sitting position, with the shoulder placed in a slight external rotation of up to 15 degrees.

Statistical analyses were performed to compare the difference between the results obtained at admission and after treatment with extracorporeal shock wave therapy. The obtained data were analysed with statistical computer program SPSS 23.0 for Windows. Numerical notation was represented by arithmetic mean, standard deviation, median, and interquartile range. The Wilcoxon-Matcher Pairs test was used to compare the analyzed variables after and before treatment. Values of  $p < 0.05$  were taken as statistically significant.

## Results

Thirteen subjects, patients with calcifying tendonopathy of the rotator cuff of the shoulder, participated in the study. The gender structure of the respondents consisted of 8 female patients and 5 male patients.

The average age of the respondents was  $54.8 \pm 13.8$  years. The youngest patient was 36 years old, the oldest was 71 years old. Body Mass Index values range from 20.6 to 32.7 kg / m<sup>2</sup>, with an average value of  $27.5 \pm 3.4$  kg / m<sup>2</sup>.

**Table 1.** Characteristics of the respondents.

<b>Variable</b>	
<b>sex (n%)</b>	
Female	8 (61.54)
Male	5 (38.46)
<b>age (mean <math>\pm</math> SD) (min-max)</b>	
	(54.53 $\pm$ 13.8) (36 – 71)
<b>BMI (mean <math>\pm</math> SD) (min-max)</b>	
	(27.53 $\pm$ 3.4) (20.6 – 32.7)
<b>Treated shoulder (n%)</b>	
Right	12 (92.3)
Left	1 (7.7)

At admission and after treatment, patients were analysed for their subjective perception of pain intensity using the VAS scale. According to the results, at the admission the intensity of pain was usually quantified with a score of 7 (5/13), while at the end of treatment (discharge), patients usually rated the pain with a score of 2 (6/13).

The mean score for admission pain was  $7.9 \pm 1.4$ , the mean score was 8, at the end of treatment (discharge) the VAS scale had a mean value of  $2.6 \pm 1.6$ , the mean value was 2. Statistical analysis identified a significant difference in the VAS scale at the end of treatment (outs) in relation to admission

( $p = 0.0015$ ). At the end of treatment, patients had significantly less pain compared to their perception of pain intensity on admission

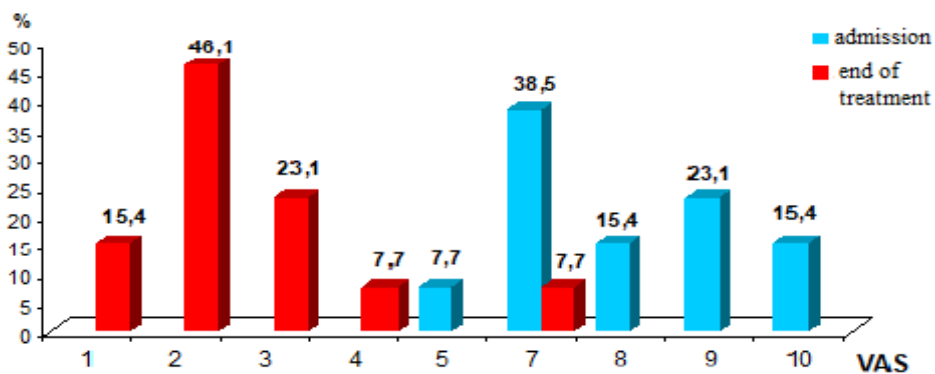
**Table 2.** VAS scale at admission and after treatment.

VAS	Admission (n%)	End of treatment (n%)
1		2 (15.38)
2		6 (46.15)
3		3 (23.08)
4		1 (7.69)
5	1 (7.69)	
7	5 (38.46)	1 (7.69)
8	2 (15.38)	
9	3 (23.08)	
10	2 (15.38)	

**Table 3.** Statistical analysis of VAS at the end of treatment in relation to admission

VAS	Descriptive Statistics (VAS)			p value
	mean $\pm$ SD	min – max	median (IQR)	
Admission	7.92 $\pm$ 1.4	5 – 10	8 (7 – 9)	Z=3.18
End of treatment	2.61 $\pm$ 1.6	1 – 7	2 (2 – 3)	p=0.0015 sig

p(Mann-Whitney U Test)



**Fig.1.** VAS scale at admission and after treatment.

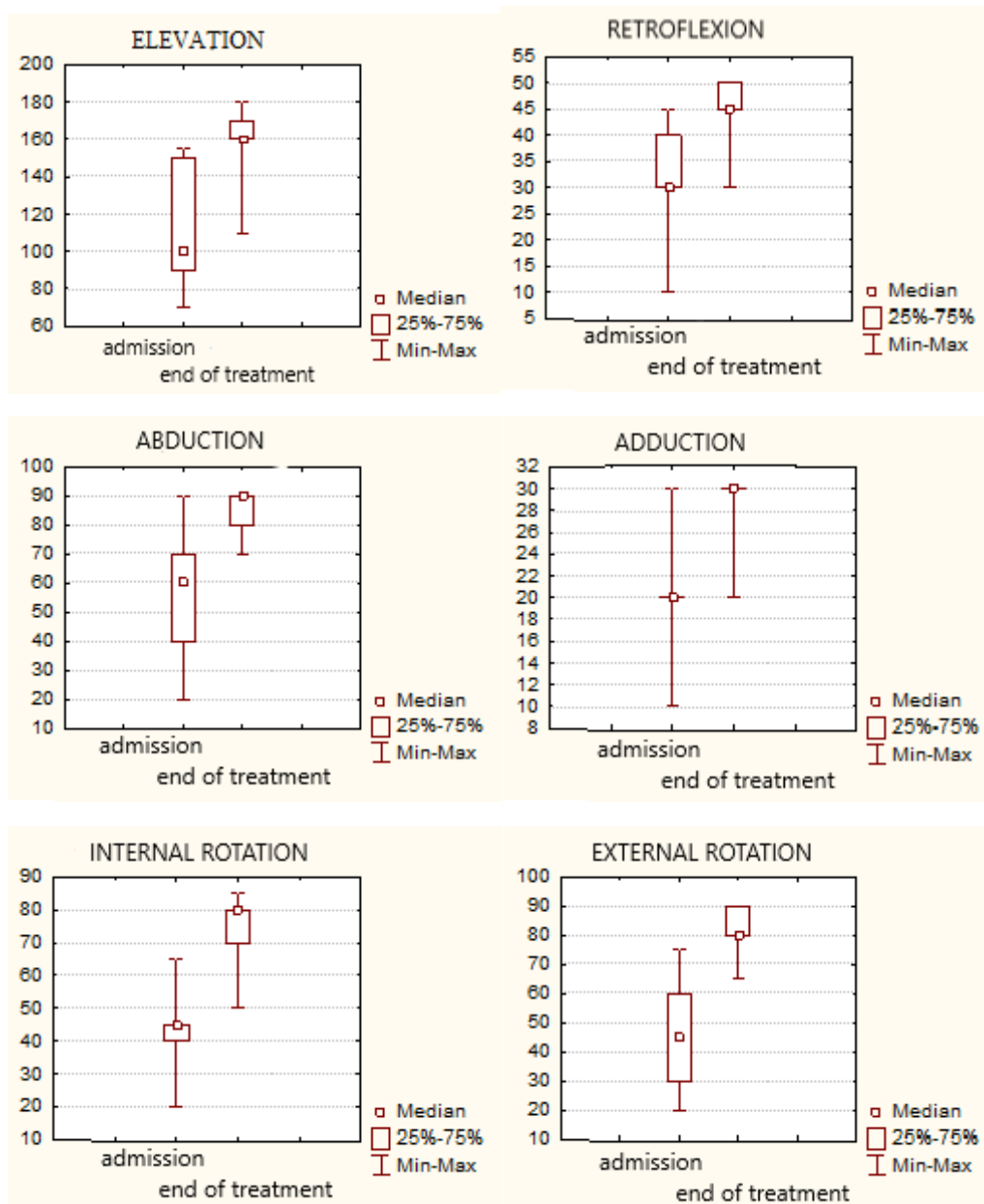
All analysed movements in the shoulder after the treatment were increased, i.e. improved. The test difference comparatively after completion of treatment / admission was statistically significant for all shoulder movements: elevation ( $p = 0.0015$ ), retroflexion ( $p = 0.0015$ ), abduction ( $p = 0.002$ ), adduction ( $p = 0.002$ ), internal and external rotation ( $p = 0.0015$ ). The average values of admission and

after the end of the treatment were:  $115.77 \pm 33.1$  and  $163.08 \pm 17.9$  degrees, respectively, for elevation;  $31.92 \pm 9.7$  and  $45.38 \pm 5.9$ , respectively, for retroflexion;  $56.15 \pm 22.2$  and  $85.77 \pm 6.4$ , respectively, for abduction;  $19.61 \pm 5.2$  and  $28.46 \pm 3.7$ , respectively, for adduction;  $44.23 \pm 12.1$  and  $74.61 \pm 10.1$ , respectively, for internal rotation;  $45.77 \pm 19.7$  and  $81.15 \pm 7.7$ , respectively, for external rotation.

**Table 4.** Statistical analysis of movements at admission and after treatment.

		Descriptive Statistics			p value
		mean $\pm$ SD	min – max	median (IQR)	
elevation 0-180°	admission	$115.77 \pm 33.1$	70 – 155	100(90 – 150)	Z=3.18
	end of treatment	$163.08 \pm 17.9$	110 – 180	160(160 – 170)	p=0.0015 sig
retroflexion 0-50°	admission	$31.92 \pm 9.7$	10 – 45	30(30 – 40)	Z=3.18
	end of treatment	$45.38 \pm 5.9$	30 – 50	45(45 – 50)	p=0.0015 sig
abduction 0-90°	admission	$56.15 \pm 22.2$	20 – 90	60(40 – 70)	Z=3.06
	end of treatment	$85.77 \pm 6.4$	70 – 90	90(80 – 90)	p=0.0022 sig
adduction 0-30°	admission	$19.61 \pm 5.2$	10 – 30	20(20 – 20)	Z=3.06
	end of treatment	$28.46 \pm 3.7$	20 – 30	30(30 – 30)	p=0.0022 sig
internal rotation 0-85°	admission	$44.23 \pm 12.1$	20 – 65	45(40 – 45)	Z=3.18
	end of treatment	$74.61 \pm 10.1$	50 – 85	80(70 – 80)	p=0.0015 sig
external rotation 0-90°	admission	$45.77 \pm 19.7$	20 – 75	45(30 – 60)	Z=3.18
	end of treatment	$81.15 \pm 7.7$	65 – 90	80(80 – 90)	p=0.0015 sig

Z (Wilcoxon Matched pairs test)



**Fig.2.** Elevation, retroflexion, abduction, adduction, internal and external rotation.

### Discussion

Calcifying rotator cuff tendinitis is a common condition of disability, often chronic and recurrent. It is the leading cause of shoulder pain with a prevalence of 5-39% in the general population[6].

There is a consensus in the literature that the primary treatment for calcifying tendinitis of the rotator cuff shoulder should be conservative treatment. The literature recommends a minimum of 6 months of nonoperative conservative treatment before considering surgical treatment [7].

ESWT is an effective modality treatment that reduces pain and increases function, especially in chronic shoulder tendon injuries [8].

The mean age of patients in this study was  $54.8 \pm 13$  years. In the literature, calcifying tendinitis of the rotator cuff is most common in people between the ages of 30 and 60.[9]

In terms of gender structure, the study included 8 female patients and 5 male patients. Women are more often affected than men, with studies finding that 70% of calcifying tendinitis occurs in female patients.[10]

The study included patients with body mass index values ranging from 20.6 to 32.7 kg/m<sup>2</sup>, with an average value of 27.5 ± 3.4. Wendelbo et al. stated that an increase in BMI is a risk factor for rotator cuff tendinitis and similar conditions [11].

Given all this, it is considered that external factors such as age and BMI have been shown to be associated with shoulder pain in CTRC. Increased pain with age is thought to be closely related to partial rupture of the rotator cuff muscle fibers, but abnormal BMI has also been suggested as a risk factor for the development of rotator cuff fibers or for the development of tendinopathy [12].

Various medical treatments, injections, physical modalities and surgical methods are used in the treatment of the rotator cuff [13].

In this study, extracorporeal shock wave therapy was used as a newer conservative method.

Conservative treatments are quite effective in improving the symptoms of calcifying tendinitis of the rotator cuff in most cases, as reported by Cho et al. who had excellent to good results in 72% of their patients [14].

In another study, Rebuzzi et al. compared the results of treatment with arthroscopic surgery with low energy ESWT in homogeneous calcification of supraspinatus. The rate of complete disappearance of calcification associated with arthroscopic surgery was 86.35% compared with the ESWT group with 58.33% after two years, but with no significant difference in clinical and functional assessment according to the UCLA scale. This leads the authors to the conclusion that they prefer the use of ESWT as the first option for therapeutic choice as a non-invasive method [15].

The primary advantage of extracorporeal shock wave therapy is its non-invasive nature and seemingly minimal complications when applied to the musculoskeletal system. Experimental in vitro studies of tendon tissues have shown local neoangiogenesis associated with increased anti-inflammatory cytokines and growth factors following shock wave administration, followed by cell proliferation and increased metabolism [16-17].

Conservative treatment for calcifying tendinitis of the rotator cuff of the shoulder has been shown to provide significant improvement regardless of the location, type, size, and initial symptoms of calcification deposits. Chu et al. [18] reported that of 241 shoulders with symptomatic calcifying tendinitis of the rotator cuff treated with ESWT, complete resorption and incomplete resorption of calcifications was observed in 134 and 107 shoulders, respectively. Complete relief of symptoms occurred in 81% of the shoulders with complete resorption and 23.4% in those with incomplete resorption.

Thirteen patients with calcifying rotator cuff tendinitis alone were included in this study, although ESWT is considered to be an alternative treatment for calcifying and non-calcifying rotator cuff tendinitis that will reduce the need for surgery. Husstede et al. evaluated 17 studies on the efficacy of ESWT application in rotator cuff tendinitis. Eleven of them were for calcifying and six for non-calcifying tendinitis of the rotator cuff of the shoulder. At the end of their study, they received evidence that ESWT was more effective than placebo and other treatment modalities in the treatment of CTRC, but not in non-calcifying tendinitis [19].

In this study low energy was applied with radial extracorporeal shock wave therapy though. In terms of energy level, the tendency is to take into account that higher energy is more effective in the treatment of calcification.

In 2014 Verstraelen et al., in the *Clinical Orthopedics and Related Research* published a meta-analysis that confirmed the concept and concluded that the use of high energy determines a higher rate of calcification resorption and a better functional response, but treatment is painful, more expensive and sometimes requires hospital treatment.

However, the rapid growth of radial ESWT in recent years has positioned it as an alternative to focal ESWT for treatment. Cacchio et al. report a high rate of calcification reabsorption using radial ESWT in a randomized controlled study. Time will tell if radial shock waves have the same efficiency standards compared to focal shock waves [20].

In this study, the mean score for VAS before starting CTRC treatment on the shoulder was 7.9 ± 1.4, the mean score was 8, and at the end of treatment VAS scale had a mean value of 2.6 ± 1.6, mean value of 2. Statistical analysis identified a significant difference in VAS scale after completion of

treatment in terms of admission ( $p = 0.0015$ ). At the end of the treatment, patients had significantly less pain compared to their perception of the intensity of pain on admission. There are studies showing that ESWT is effective in reducing pain in patients with CTSC on the shoulder involving pulses ranging from 0.28 to 0.45 mJ/mm<sup>2</sup>[21] In a study by Malliaropoulos et al. evaluating an individualized radial ESWT protocol for the treatment of symptomatic calcifying tendinitis of the rotator cuff shoulder, the authors reported a success rate of 92% at 12-month follow-up, 52% reduction in mean VAS immediately after treatment, 62% after month and 75% after three months. This improvement of symptoms persisted for one year with an average 88% reduction in VAS from baseline at 12 months, and only a 7% recurrence rate (mean VAS before treatment decreased from 4.7 to mean VAS after treatment 2.4 during a six-month follow-up)[22].

The efficacy of ESWT in calcifying shoulder tendinitis was analysed in a study by Wang et al., which lasted 30 months, where two groups were prospectively compared: the ESWT group had 90.9% excellent or good results, 3% satisfactory and 6.1% bad results, and complete disappearance of calcification in 57.6%, partial in 15.1% and no change in 27.3%. ESWT-placebo group 16.7% satisfactory results and 83.3% poor results. This study showed that ESWT is a safe and effective, non-invasive treatment for patients with calcifying tendinitis of the shoulder [23].

In this study, all analysed shoulder movements after the completed treatment were increased, i.e. improved. The test difference comparatively after completion of treatment / admission was statistically significant for all shoulder movements: elevation ( $p = 0.0015$ ), retroflexion ( $p = 0.0015$ ), abduction ( $p = 0.002$ ), adduction ( $p = 0.002$ ), internal and external rotation ( $p = 0.0015$ ).

In addition, no adverse reactions were observed in patients associated with the application of low-energy extracorporeal shock therapy. ESWT does not cause damage to the cartilage of the joints and has no thermal effect. The effect also depends on the amount of energy applied to the tissue.

This study has several limitations. Patients were evaluated twice, at the beginning of treatment and at the end of treatment; however, long-term follow-up was not performed to assess the success of therapy. In addition, treatment success was not assessed through diagnostic techniques in terms of localization and size of the calcification, but was assessed in terms of shoulder pain and range of motion, which affects shoulder joint function.

### Conclusion

Radial ESWT is a non-invasive, safe and effective method of treating CTSC on the shoulder, which allows early reduction of pain and improvement of the range of motion in the shoulder.

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