

## **Focused Extracorporeal Shockwave Therapy in Non-Calcific, Adhesive Capsulitis: A Randomized Double-Blind Controlled Trial**

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### **ABSTRACT**

**Objectives:** To study the efficacy of focused extracorporeal shockwave therapy (f-ESWT) combined with an exercise program to reduce pain, improve function, and increase range of motion (ROM) in patients with non-calcific, adhesive capsulitis (NCAC) of the shoulder.

**Study design:** A randomized double-blind controlled trial.

**Setting:** An out-patient rehabilitation clinic.

**Subjects:** Patients with a confirmed diagnosis of NCAC

**Methods:** Patients were randomly allocated to either f-ESWT (experimental) or sham (control) groups. The f-ESWT group ( $n = 14$ ) received f-ESWT whereas the sham group ( $n = 12$ ) received a sham ESWT once a week for 6 weeks. A weekly individualized supervised home-based exercise program was provided to participants in both groups. The numeric rating scale of pain (score 0-10), the Shoulder Pain and Disability Index (SPADI) questionnaire and shoulder ROM were evaluated prior to and at 2, 4, 6, and 10 weeks after the initial treatment.

**Results:** The numerical rating scale of pain, the functioning SPADI score, and shoulder ROM were significantly improved in both groups. Improvement was significantly apparent at the 2<sup>nd</sup> and the 4<sup>th</sup> week after treatment and continued through the 10<sup>th</sup> week of follow-up. However, there was no significant difference in any of the measured outcomes between the two groups.

**Conclusions:** In treating non-calcific adhesive capsulitis shoulder, f-ESWT plus exercise is not superior to a home exercise program alone in reducing pain, improving function, and increasing ROM.

**Keywords:** extracorporeal shockwave therapy, bursitis, adhesive capsulitis, pain, exercise therapy

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### **Introduction**

Adhesive capsulitis (AC) or frozen shoulder is a common problem characterized by pain and stiffness in the shoulder joint which causes limitation of activities in daily living. The exact cause is not clearly understood, especially in idiopathic

AC, but is generally considered to be a result of scarring, thickening, and shrinkage of the joint capsule. Although AC is a self-limiting condition in which the symptoms gradually resolve over a period of 1-3 years, the estimated substantial burden, both to patients and to society, suggests that effective early treatment of AC is warranted in order to attempt to accelerate recovery and to prevent complications.<sup>1</sup> Treatment is focused on symptomatic relief of pain and improvement in shoulder range of motion (ROM). There has been no consensus regarding the scientific evidence for the efficacy of any single treatment for AC, although there is a general agreement that non-operative management is the initial treatment of choice for AC. Physical therapy programs, including various modalities and exercises, are considered to be able to relieve pain and restore shoulder motion.<sup>2,3</sup>

Extracorporeal shockwave therapy (ESWT) is a widely known emerging modality which has become a leading choice in the treatment of various orthopedic disorders, including plantar fasciitis,<sup>4</sup> lateral epicondylitis,<sup>5</sup> and calcific tendinitis of the shoulder.<sup>6</sup> However, its clinical efficacy in treating non-calcific tendinopathy of the shoulder remains controversial.<sup>7</sup> The shock waves in ESWT are characterized by high peak-pressure amplitudes (500 bar) with rise times of less than 10 ns, a short lifecycle (< 10 ms), and a frequency spectrum ranging from 16 Hz to 20 MHz.<sup>8</sup> There are several available shock wave generators, including piezoelectric systems that are characterized by piezoelectric crystals mounted to a spherical surface producing a focused pressure pulse which is created by the geometrical shape of the sphere.<sup>9</sup> Although the mechanisms by which the shock wave induces a biological effect is not fully understood, it is hypothesized that the mechanotransduction is a response to mechanical stimulation converting physical forces into biochemical signals which stimulate extracellular matrix binding proteins and nucleus via the cell cytoskeleton, leading to tissue regeneration. Effects include enhanced neovascularity, accelerated growth factor release, selective neural inhibition, and inhibition of molecules that have a role in inflammation.<sup>10,11</sup>

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These findings suggest that ESWT could potentially have a positive effect on the healing of chronic tendinosis which is characterized by hypovascularity.

In the treatment of shoulder pathology, ESWT has been demonstrated to be effective in pain reduction and providing functional improvement of calcific tendinitis.<sup>12,13</sup> However, recent evidence has provided inconsistent results for ESWT in the treatment of non-calcific AC (NCAC) of the shoulder.<sup>14-16</sup> Currently, there is no consensus as to which treatment is the most effective for AC, although according to recommendations of the Philadelphia Panel, therapeutic exercise seems to be an acceptable intervention.<sup>17</sup> A systematic review of 39 studies found that a combination of therapeutic exercises and mobilization therapy were strongly recommended for reducing pain and improving ROM and function in patients with AC stages 2 and 3.<sup>18</sup>

There is still controversy regarding the efficacy of combined exercise and f-ESWT in the treatment of shoulder pathology,<sup>19,20</sup> and there have been no studies of NCAC. This study aimed to investigate the efficacy of f-ESWT combined with home-based exercise in the treatment of NCAC and to compare that to a home-based exercise program alone.

## Methods

### Study design

This study, a randomized double blinded (patient and assessor) controlled trial, was approved by the institute's ethical committee and was registered with the clinical trial registry [Registry number TCTR20160810002]. It was conducted from July 2016 to August 2017 in an outpatient rehabilitation setting. All enrolled subjects provided written informed consent prior to participation.

### Participants

Patients who met the following criteria were recruited: (i) diagnosis of unilateral AC without calcification as determined by physical examination, ultrasonography, and/or magnetic resonance imaging; (ii) age over 18 years, (iii) shoulder pain with a numeric rating of at least 4 (from a maximum score of 10); (iv) restricted shoulder ROM in at least two directions, including external rotation; (v) no alternative therapy, including injection and ESWT, within a month prior to enrollment in the study. Patients were excluded if they had a massive rotator cuff tear, calcific tendinopathy, or a history of trauma, tumors, surgery, uncontrolled systemic diseases or neuromuscular disorder.

Sample size was determined using the pre- and post-treatment Shoulder Pain and Disability Index (SPADI) score from Vadathpur et al.,<sup>21</sup> with an assumed study power of 90% ( $\beta = 0.10$ ) and a statistical significance level of 5% ( $\alpha = 0.05$ ). The calculated required sample size was 13 patients per group.

### Randomization and blinding

Randomization was done by computer, with patients assigned to receive either actual f-ESWT (experimental group) or sham ESWT (control group) at a 1:1 ratio. All assignments were concealed in sequentially numbered, opaque sealed envelopes. The patients and the assessor (one of the investigators) were blinded to the treatment allocation.

### Interventions

The piezoelectric shockwave device (Swiss Piezoclast, EMS Electro Medical System S.A., Nyon, Switzerland) was used for f-ESWT. Patients were treated in a sitting position with the affected shoulder in internal rotation. They received f-ESWT with a total of 1,500 pulses of 0.1-0.3 mJ/mm<sup>2</sup> (adjusted to the individual patient's tolerance) at a frequency of 8 Hz.<sup>22</sup> The gel pad applicator penetration depth was either 15 mm or 20 mm depending on the patient's body mass index (BMI) (15 mm for BMI < 25, and 20 mm for BMI > 25). The f-ESWT probes were placed at three sites around the shoulder joint as follows: (i) anterior, one finger breath lateral to the coracoid process; (ii) lateral, one finger breath below the acromion tip; and (iii) posterior, under the lateral border of the scapular spine. A total of 500 pulses were given at each area, for a total of 1,500 pulses per session. Patients received this treatment once a week for over a six-week period (six sessions).

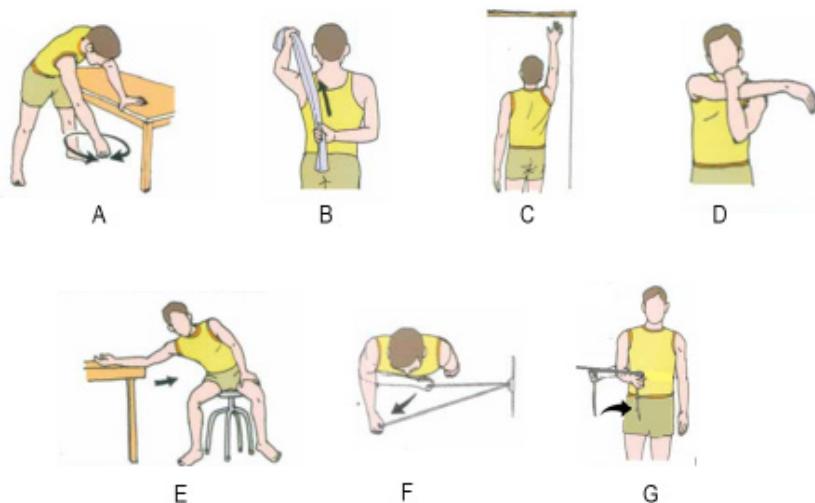
Patients in the control group received sham ESWT treatment using an identical-appearing probe. The patient was shielded from the shock wave by a polyethylene foil sheet placed between the silicone pad and the shockwave probe. The probe emitted the same sounds as the ESWT probe. All other procedures in the sham (control) group were the same as in the experimental group.

### Exercise programs (Figure 1)

Patients in both groups were instructed in a home-based exercise program by a physical therapist who was blinded to group allocation. The therapist advised each patient individually and scheduled a weekly follow-up appointment (a total of six times) during which the therapist prescribed/demonstrated the exercises step-by-step according to individual patient's symptoms. The program included five stretching exercises (pendulum stretch, towel stretch, finger walk, cross-body reach and armpit stretch) and two strengthening exercises (outward rotation and inward rotation) (Figure 1).

The patients also received a leaflet with pictures of the seven exercises and were advised to repeat all seven exercises 5-10 times daily at home and to record the exercises in an exercise diary.

They were provided acetaminophen and were told they were allowed to take 1-2 tablets 500 mg/tablets every 8 h for a maximum of 6 tablets/day, and were instructed to record their tablet intake. No other drug or pain therapy was allowed during the study.



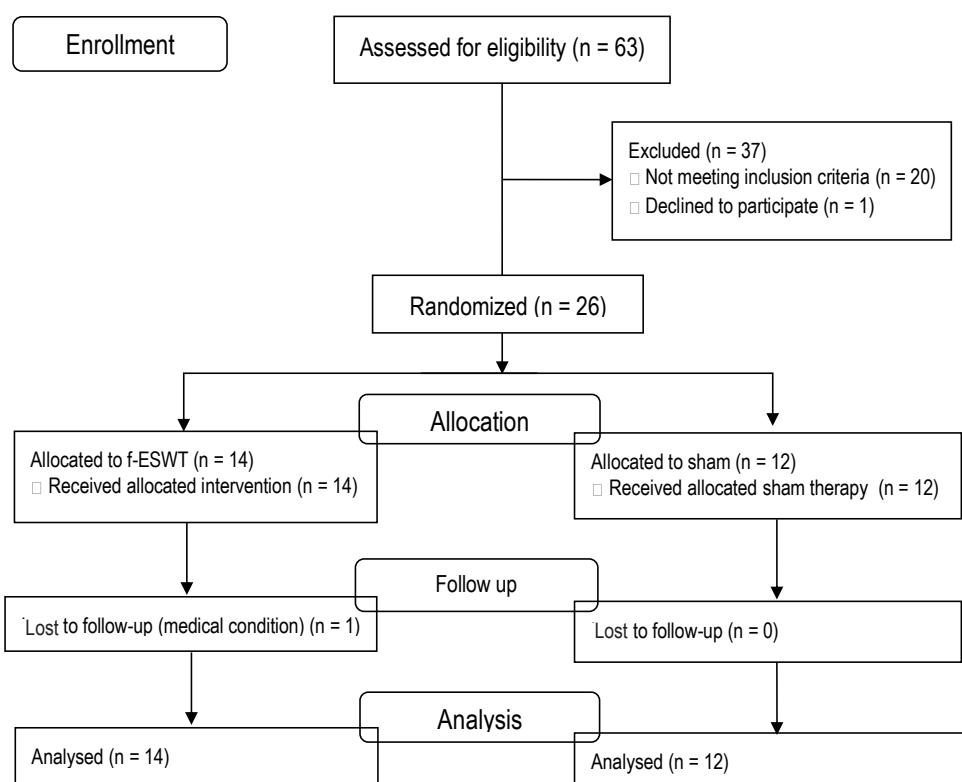
**Figure 1.** Exercise program activities.

Stretching:

- A) pendulum stretch,
- B) towel stretch,
- C) finger walk,
- D) cross-body reach,
- E) armpit stretch;

Strengthening:

- F) outward rotation,
- G) inward rotation



**Figure 2.** Consort diagram showing participants' progress through the phases of the study

### Outcome measurements

A well-trained physical therapist who was blinded to the patients' treatment group was assigned to measure and document outcomes at baseline, and at 2, 4, 6, and 10 weeks after the first treatment as follows:

1. Shoulder Pain and Disability Index (SPADI):<sup>23</sup> a self-administered questionnaire that contained a total of 13 items in two subscales, pain and functional activities. The pain subscale consisted of five items related to the severity of the individual's pain. Functional activities were assessed with eight items designed to measure the degree of difficulty an individual has with various activities of daily living that require upper-limb use. Each of the 13 items was scored on a numeric rating scale (NRS) of 0-10 where 0 = no pain and 10 = the worst pain imaginable. The scores from each of the

subscale were combined to give a maximum score of 50 for each subscale and a total score of 100 for the two subscales together.

The SPADI questionnaire had previously been demonstrated to have good internal consistency, test-retest reliability, and criterion and construct validity. It also appeared to be able to detect changes in the patient's status over time.<sup>23</sup>

2. Range of motion (ROM): the involved shoulder was measured using a goniometer for flexion, abduction, and extension plus internal and external rotation.

### Statistical methods

The data were analyzed using the Statistical Package for the Social Sciences version 22.0 (SPSS Inc., Chicago, Illinois). Demographic data are shown as mean and standard

**Table 1.** Baseline demographics and clinical characteristics of the patients in this study

	f-ESWT group (n = 14)	Sham (n = 12)	p-value
Age (years) <sup>1</sup>	59.9 (8.9)	55.9 (7.3)	0.532 <sup>a</sup>
Female gender <sup>2</sup>	10 (71.4)	9 (75.0)	0.555 <sup>b</sup>
BMI (kg/m <sup>2</sup> ) <sup>1</sup>	22.8 (3.7)	22.9 (3.3)	0.955 <sup>a</sup>
Duration of symptoms (months) <sup>1</sup>	6.4 (4.3)	6.2 (3.5)	0.869 <sup>a</sup>
Affected side, right <sup>2</sup>	6 (42.9)	4 (33.3)	0.635 <sup>b</sup>
Dominant side, right <sup>2</sup>	13 (92.9)	11 (91.7)	0.829 <sup>b</sup>
NRS pain <sup>1</sup>	6.4 (1.8)	6.7 (1.3)	0.710 <sup>a</sup>
SPADI:			
SPADI-pain <sup>1</sup>	23.1 (10.1)	22.1 (6.9)	0.777 <sup>a</sup>
SPADI-disability <sup>1</sup>	38.0 (15.9)	31.3 (11.7)	0.236 <sup>a</sup>
SPADI-total <sup>1</sup>	61.1 (24.6)	53.3 (17.2)	0.370 <sup>a</sup>
Range of motion:			
Flexion <sup>1</sup>	120.2 (23.8)	126.2 (21.1)	0.457 <sup>a</sup>
Abduction <sup>1</sup>	100.0 (24.6)	105.4 (27.6)	0.863 <sup>a</sup>
External rotation <sup>1</sup>	34.4 (12.9)	33.7 (17.9)	0.911 <sup>a</sup>
Internal rotation <sup>1</sup>	38.5 (21.8)	35.9 (24.7)	0.780 <sup>a</sup>

<sup>1</sup>Mean (SD), <sup>2</sup>number (%); <sup>a</sup>Unpaired T test, <sup>b</sup>Chi-square test

BMI, body mass index; NRS, Numeric rating scale; SPADI, Shoulder Pain and Disability Index

deviation (SD) or percentage. For comparison of the baseline characteristics between the two groups, the unpaired t-test or chi-square test was performed as appropriate. For intra-group comparisons between pre-treatment and at 2, 4, 6, and 10 weeks after the first treatment, repeated ANOVA was performed, while two-way ANOVA was performed for inter-group comparisons. Analyses were conducted according to the intention-to-treat principle. Statistical significance was accepted at the  $p < 0.05$  level.

## Results

A total of 63 patients were assessed for eligibility of whom 26 were recruited into the study. Fourteen patients were randomly allocated to the f-ESWT group and 12 to the sham (control) group. Figure 2 shows a schematic flow chart of the participants, reasons for exclusion and follow-up throughout the study. The patients' mean age was 58.04 years and the mean symptom duration prior to the study was 6.31 months. Seventy-three percent of the subjects were women.

The baseline demographic and clinical characteristics of patients in the f-ESWT and the sham (control) groups were compared as shown in Table 1. No significant differences were observed between the two groups. One subject in the f-ESWT group was lost to follow-up due to a subsequent medical condition.

In both groups, there was significant improvement in the NRS and SPADI scores and in ROM between pre- and post-treatment. The f-ESWT group showed early improvement in the SPADI disability subscale and the flexion ROM at 2 weeks after the 1<sup>st</sup> treatment, but there was no significant difference in the mean change between the two groups (Table 2). Two patients in the sham (control) group reported taking acetaminophen tablets, but none in the f-ESWT group did so. The average energy flux density used in the f-ESWT

group was  $0.16 \pm 0.07 \text{ mJ/mm}^2$ . No complications were found in either group.

## Discussion

This randomized controlled trial investigated the efficacy of f-ESWT in the treatment of NCAC. It was found that the f-ESWT group showed early improvement, but that there was no significant difference in clinical outcomes between the experimental and the control groups, i.e., there was no evidence that f-ESWT plus home-based exercise had a more beneficial effect than home-based exercise alone in patients with NCAC.

The results of our study are concordant with previous studies of ESWT in other non-calcific shoulder pathologies,<sup>24,25</sup> although, in contrast to the present study, none of those studies used f-ESWT. A recent systematic review by Surace et al.<sup>26</sup> concluded that there were very few clinically important benefits of ESWT for rotator cuff disease either with or without calcification based on currently available low-to moderate-certainty evidence due to the diversity of treatment protocols used. A standard treatment protocol has yet to be determined.

A few studies have investigated the efficacy of ESWT in the treatment of AC,<sup>21,22,27</sup> but more evidence is needed to draw conclusions regarding its effectiveness.<sup>7</sup> To the best of our knowledge, this study is the first to incorporate f-ESWT as the only intervention along with a supervised home-based exercise program in the treatment of NCAC in a comparison with a sham f-ESWT plus supervised home-based exercise. A 2014 study examined 40 patients with primary AC randomized between f-ESWT and oral steroid treatment, but with no sham group.<sup>22</sup> In that study, both groups showed improvement in short-term functional outcomes, but the group receiving f-ESWT showed faster and greater improvement.

**Table 2.** Comparison of outcome data of numeric rating scale (NRS), shoulder pain and disability index (SPADI) score and range of motions (ROMs) at 2, 4, 6, and 10 weeks after the first treatment between the f-ESWT and the sham groups

Outcomes	f-ESWT (n = 14)		Sham (n = 12)		Mean difference between group (95% CI)	Time* group effect	
	Mean (SD)	Mean difference from baseline (95% CI)	Mean (SD)	Mean difference from baseline (95% CI)		F	p-value
NRS						0.184	0.946
2 week	5.7 (0.5)	-0.6 (0.7,-2.1)	5.5 (0.4)	1.2 (0.4,-2.7)	0.3 (-1.2,1.8)		
4 week	4.1 (0.6)	-2.5 (-0.4,-4.5)*	3.8 (0.3)	-2.8 (-1.5,-4.1)*	0.3 (-1.2,1.8)		
6 week	2.4 (0.5)	-4.3 (-3.3,-6.2)*	2.7 (0.5)	-3.9 (-2.0,-5.7)*	0.3 (-1.9,1.2)		
10 week	2.2 (0.4)	-4.5 (-2.5,-6.5)*	2.0 (0.3)	-4.7 (-3.4,-5.9)*	0.2 (-1.0,1.5)		
SPADI-total						0.288	0.885
2 week	52.5 (6.7)	-9.2 (-.01,-18.2)*	46.08 (5.17)	-7.3 (1.5,-16.0)	6.5 (-11.4,24.4)		
4 week	32.7 (5.6)	-30.5 (-14.0,-47.0)*	33.42 (4.64)	-19.9 (-9.5,-30.3)*	0.7 (-16.1,14.7)		
6 week	21.0 (5.1)	-43.1 (-24.5,-61.6)*	22.00 (3.05)	-31.3 (-12.6,-50.1)*	0.9 (.13.8,12.0)		
10 week	17.5 (5.1)	-46.7 (-23.5,-70.2)*	15.25 (2.43)	-38.1 (-23.1,-53.0)*	2.3 (-10.1,14.7)		
SPADI-pain						0.210	0.932
2 week	19.1 (2.8)	-3.6 (-1.9,-9.1)	18.25 (2.24)	-3.8 (1.0,-8.6)	1.6 (-6.13,9.09)		
4 week	11.7 (2.3)	-12.2 (-2.4,-22.1)*	12.42 (1.92)	-9.7 (-4.9,-14.3)*	0.7 (-7.12,5.72)		
6 week	7.0 (1.8)	-17.2 (-8.1,-26.4)*	9.08 (1.96)	-13.0 (-5.4,-20.5)*	2.0 (-7.53,3.50)		
10 week	5.8 (1.8)	-18.5 (-8.9,-28.2)*	5.25 (1.23)	-16.8 (-11.6,-22.1)*	0.6 (-4.08,5.29)		
SPADI-disability						0.351	0.843
2 week	32.8 (4.1)	-5.5 (-1.1,-9.9)*	27.83 (3.21)	-3.4 (1.5,-8.4)	5.0 (-6.0,16.1)		
4 week	21.0 (3.5)	-18.3 (-9.1,-27.5)*	21.00 (3.09)	-10.2 (-3.4,-17.1)*	0.0 (-9.9,9.9)		
6 week	14.0 (3.4)	-25.8 (-14.0,-37.7)*	12.92 (1.68)	-48.3 (-6.5,-30.1)*	1.0 (-7.3,9.5)		
10 week	11.7 (3.4)	-28.3 (-13.4,-43.2)*	10.00 (1.50)	-21.2 (-9.9,32.5)*	1.7 (-6.5,9.9)		
ROM-flexion						0.443	0.777
2 week	138.6 (4.8)	19.8 (1.9, 37.8)*	133.0 (6.4)	6.9 (-0.5, 14.3)	5.5 (-10.8,21.9)		
4 week	149.0 (4.4)	31.0 (11.5, 50.5)*	142.9 (6.6)	16.7 (6.5, 27.0)*	6.1 (-9.9,22.1)		
6 week	158.8 (4.3)	34.1 (14.7, 53.5)*	151.9 (6.9)	25.7 (11.7, 39.7)*	0.1 (-16.5,16.3)		
10 week	153.8 (4.7)	36.2 (14.3, 58.1)*	157.5 (6.4)	31.3 (14.6, 48.1)*	3.6 (-19.7,12.5)		
ROM-abduction						0.219	0.927
2 week	115.1 (5.6)	12.0 (-0.5, 24.7)	111.7 (7.8)	6.3 (-1.4, 14.1)	3.3 (-16.2,22.8)		
4 week	126.2 (5.9)	24.1 (8.7, 39.6)*	121.8 (7.3)	16.4 (3.0, 29.8)*	4.4 (-14.8,23.7)		
6 week	135.6 (6.9)	34.2 (16.3, 52.2)*	137.7 (7.4)	32.3 (5.4, 59.3)*	2.1 (.23.1,18.9)		
10 week	139.7 (7.9)	36.2 (11.6, 65.7)*	146.9 (8.3)	41.5 (9.9, 73.1)*	7.1 (-30.9,16.7)		
ROM-internal rotation						0.259	0.904
2 week	41.7 (4.1)	7.9 (-1.3, 17.2)	36.3 (5.4)	6.3 (-2.9,8.2)	5.3 (-8.6,19.3)		
4 week	50.7 (4.9)	17.7 (6.9, 28.5)*	49.4 (5.5)	16.4 (4.8, 26.7)	1.3 (-13.9,16.6)		
6 week	55.7 (5.3)	23.0 (8.9, 37.2)*	56.0 (5.1)	22.4 (8.87,35.9)	0.3 (-15.7,15.2)		
10 week	61.1 (5.5)	28.8 (12.3,45.3)*	65.9 (5.5)	32.2 (12.8,44.0)	4.7 (-21.0,11.4)		
ROM-external rotation						0.103	0.981
2 week	45.3 (6.0)	7.4 (-3.9,18.2)	41.1 (7.8)	5.2 (-2.7,13.2)	4.1 (-15.9,24.3)		
4 week	54.4 (5.6)	17.2 (5.4,28.9)*	52.8 (7.7)	16.9 (2.3,31.5)*	1.6 (-17.7,20.9)		
6 week	59.9 (5.1)	23.1 (11.7,34.6)*	56.9 (6.3)	21.0 (6.7,35.3)*	3.0 (-13.7,19.7)		
10 week	61.1 (5.3)	24.3 (11.6,37.0)*	64.3 (6.5)	28.4 (12.8,44.0)*	3.2 (-20.6,14.1)		

CI, confident interval; \*p < 0.05 indicates statistical significance

Negative mean difference scores (95%CI) of NRS and SPADI are indicative of improvement, whereas positive change scores (95%CI) of ROM indicates improvement.

Our study adopted a f-ESWT protocol similar to that of Chen et al.<sup>22</sup> in terms of the locations and numbers of shots at each treatment, but we added a comparison of the effect with a sham treatment group. We also observed significant improvement, i.e., pain and SPADI score reduction and increased ROM, as early as 2 weeks after the first f-ESWT treatment, but the amount of improvement was not signifi-

cantly different from that of the sham f-ESWT (control) group for any of the outcome measures. The discrepancy between our results and those with Chen et al.<sup>22</sup> may be due to a dose-dependent effect of f-ESWT. The energy flux density (EFD) used in Chen et al.<sup>22</sup> was 0.6 mJ/mm<sup>2</sup>, which is considered a high-energy ESWT. In contrast, in our study we were unable to increase the EFD to higher levels due to the limit of the

individual patient's tolerance to pain, so the average EFD in our study was some 3.75-fold lower ( $0.16 \pm 0.07 \text{ mJ/mm}^2$ ), which is considered a low-energy ESWT. A systematic review by Bannuru et al.<sup>28</sup> categorized an EFD  $\geq 0.28 \text{ mJ/mm}^2$  as high-energy and concluded that high-energy ESWT was significantly better in decreasing pain and improving function in chronic calcific shoulder tendinitis, while no similar effect was found in non-calcific tendinitis. Additionally, high-energy f-ESWT has been reported to be an effective treatment for Duputren's disease<sup>29</sup> which historically has been classified as a fibrotic disorder akin to AC.<sup>30</sup>

In another study, Vahdatpour et al.<sup>21</sup> compared f-ESWT to sham therapy in 40 patients with a frozen shoulder. In that study, both groups were given 2-3 exercises, less than the number of exercises in our study. They also received a different sham therapy: turning off the device while placing it on the patient's shoulder. They reported that f-ESWT seemed to have a positive effect on pain and SPADI scores, with a quicker return to daily activities and improvement in the quality of life. But in that study a strong bias was introduced as both groups received an injection of 40 mg of triamcinolone into the involved shoulder joint before starting the treatment. Hussein et al.<sup>27</sup> also reported a significant improvement in functional outcome, pain level, and ROM in the treatment of radial ESWT compared to a sham group for 106 patients with AC. In both studies, a low energy EFD was used, but the location of the shockwave application was different from that used in our study. That study suggested that the anterior-posterior direction was more effective in locating adhesions. The study also stated that a more effective response was obtained with a higher energy level and appropriate session intervals. In our study, 1,500 impulses were applied to three separate locations. For that reason, we assume that the total energy for each location of the f-ESWT application in our study was insufficient to induce either an anti-inflammatory or an anti-fibrotic effect.

The comparable improvement in the pain level, ROM, and functional score in both groups in our study can be attributed to both groups using the same home-based exercise program. The physical therapist advised and tracked all of the patients in our study on a weekly basis to ensure that they were following the home-based program correctly. In a meta-analysis by Marinko et al.,<sup>31</sup> therapeutic exercise was reported to be an effective intervention for the treatment of a painful shoulder condition. Home-based exercise following the instructions of a physical therapist, including pendulum exercise, shoulder stretching, and strengthening exercises, offers a significant benefit in shoulder function improvement, pain relief, and increased ROM in patients with chronic shoulder pain<sup>32</sup> as well as in a frozen shoulder.<sup>33</sup>

In our study, patients were individually instructed on exercises tailored to their symptoms and participated in six weekly follow-up sessions with the physical therapist, which

is a larger number of sessions than in previous studies.<sup>32,33</sup> The effect of the exercises could possibly have altered the outcome and/or camouflaged the effect of the f-ESWT. Other limitations in our study include that the sample size was relatively small which might limit the generalizability of the results. Moreover, the follow-up period of only 10 weeks was relatively short. Although previous studies have found satisfactory results after a short-term follow-up, some studies have reported that improvement was still observable at a 6-month follow-up.<sup>34,35</sup>

Further studies are needed to evaluate different applications of f-ESWT in order to achieve optimal energy levels within the tolerance limits of the patient and to investigate specific responses as well as any adverse effects of f-ESWT across the various stages of AC to allow a standard treatment protocol to be established.

## Conclusions

Based on the findings of our study, low-energy f-ESWT once a week for 6 weeks plus a home-based exercise program provides no additional benefit over a home-based exercise program alone in patients with non-calcific adhesive capsulitis in terms of pain reduction, activities of daily living, and range of motion.

## Disclosure

The authors have no conflicts of interest to declare.

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