# Assessment of the Efficacy of Extracorporeal Shock Wave Therapy in Adhesive Capsulitis: Outcomes Analysis and Predictors of Recurrence

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# **Abstract**

**Background:** Adhesive capsulitis of the shoulder is a condition characterized by pain and progressive restriction of the range of motion. Its management remains a clinical challenge due to variability in therapeutic response. Extracorporeal shock wave therapy (ESWT) has emerged as a non-invasive alternative with potential antifibrotic and analgesic effects. However, evidence regarding its efficacy and the factors associated with recurrence is limited.

**Objectives:** To assess the effectiveness of ESWT in functional improvement and pain reduction in patients with adhesive capsulitis and to analyze clinical factors associated with recurrence.

**Study Design:** A retrospective observational study conducted in a cohort of patients with adhesive capsulitis treated with ESWT. The study adhered to strengthening the reporting of observational studies in epidemiology guidelines for observational research.

Materials and Methods: Nineteen patients with a clinical and image-based diagnosis of adhesive capsulitis in the inflammatory or adhesive stage, treated with ESWT at a specialized center, were included. Patients with prior shoulder surgery, inflammatory arthritis, joint infection, or full-thickness rotator cuff tear were excluded. Demographic, clinical, and therapeutic variables were analyzed.

#### **Measured Outcomes:**

- Functionality: Disabilities of the arm, shoulder, and hand (DASH) score, pre- and post-treatment
- Pain: Visual analog scale (VAS)
- Recurrence: Reappearance of symptoms requiring additional intervention within a 1-year period.

Multivariable logistic regression with Lasso regularization was used to identify predictors of recurrence.

Outcomes: Following ESWT treatment, there was a significant reduction in DASH scores ( $62.4 \pm 11.2$  pre-treatment vs.  $35.6 \pm 9.8$  post-treatment, P < 0.001) and in VAS scores (mean reduction of 3.8 points, P < 0.001). The 1-year recurrence rate was 26.3%. The following clinical factors were associated with an increased risk of recurrence:

- Advanced age (Odds ratio [OR] = 1.08, confidence interval [IC] 95%: 1.01-1.15, P = 0.02)
- Longer duration from symptom onset to the initiation of ESWT (OR = 1.23, IC 95%: 1.06–1.41, P = 0.004)
- Treatment cost as a mild protective factor (OR = 0.92, IC 95%: 0.85 0.99, P = 0.048).

No significant association was found between the number of ESWT sessions and functional improvement (r = 0.12, P = 0.34).

**Conclusion:** ESWT has demonstrated significant efficacy in improving functional outcomes and reducing pain in patients with adhesive capsulitis. Nevertheless, advanced age and delayed initiation of therapy have been identified as factors associated with an increased risk of recurrence. Early intervention is therefore recommended to optimize therapeutic outcomes. Further prospective studies with larger sample sizes and appropriate control groups are warranted to validate these findings.

**Keywords:** Adhesive capsulitis, Frozen shoulder, Extracorporeal shock waves, Extracorporeal shock wave therapy, Capsular fibrosis, Rehabilitation, Recurrence factors

#### Introduction

Adhesive capsulitis of the shoulder, commonly referred as "frozen shoulder," is a condition of multifactorial etiology characterized by severe pain and progressive restriction of both active and passive range

of motion in the glenohumeral joint. Its pathophysiology is marked by an initial phase of synovial inflammation followed by progressive fibrosis of the joint capsule, leading to significant stiffness and severe functional impairment.

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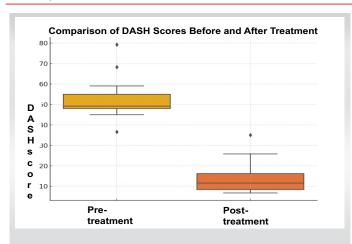
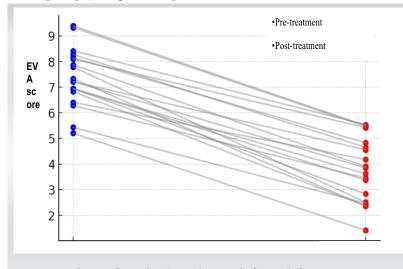


Figure 1: Comparison of disabilities of the arm, shoulder, and hand scores before and after treatment.

The condition follows a self-limiting course, typically progressing through three well-defined phases: The inflammatory or "freezing" phase, the adhesive or "frozen" phase, and the resolution or "thawing" phase. The clinical course may extend over 24–36 months, in untreated cases. Incidence is highest among individuals in their fourth to sixth decades of life. Adhesive capsulitis has been associated with metabolic conditions, such as diabetes mellitus, dyslipidemia, and thyroid disorders, suggesting a potential systemic component in its pathogenesis [1–3].

The therapeutic management of adhesive capsulitis remains challenging due to variable patient responses and the absence of a standardized treatment protocol. Conventional interventions include physical therapy, corticosteroid injections, nerve blocks, manipulation under anesthesia, and arthroscopic capsular release in refractory cases. However, treatment outcomes are inconsistent, and some patients experience recurrence or prolonged recovery. Recently, extracorporeal shock wave therapy (ESWT) has emerged as a non-invasive alternative for various musculoskeletal disorders, including adhesive capsulitis [3–5].

From a pathophysiological standpoint, the mechanism of action of



 $Figure \ 2: Evolution \ of \ V is ual \ analog \ scale \ scores \ before \ and \ after \ treatment.$ 

ESWT appears to extend beyond hyperstimulation analgesia, involving direct modulation of molecular pathways implicated in synovial fibrosis. Pre-clinical studies have demonstrated that ESWT downregulates transforming growth factor beta 1, a central mediator of myofibroblast activation and synovial fibrosis progression. In addition, ESWT reduces the expression of pro-inflammatory cytokines, such as interleukin (IL-1 $\beta$ ) and IL-6, modulating the inflammatory joint microenvironment and promoting a shift toward a regenerative phenotype. At the cellular level, ESWT inhibits capsular myofibroblast proliferation and upregulates neurogenic factors, including brain-derived neurotrophic factor, potentially accounting for both functional improvement and sustained analgesia. These findings suggest that ESWT may have disease-modifying effects by targeting the biological processes that underlie persistent pain and stiffness in adhesive capsulitis [3–5].

The mechanism of action of ESWT involves the transmission of highenergy acoustic waves that elicit a range of biologically beneficial effects, including the stimulation of angiogenesis, promotion of tissue regeneration, modulation of inflammatory responses, and inhibition of fibroblast proliferation within the joint capsule. These effects may contribute to the reduction of capsular fibrosis and enhancement of joint mobility, supporting the role of ESWT as a potential adjunct or alternative therapy in selected stages of adhesive capsulitis [4,6-8].

Despite growing clinical use, the evidence supporting the efficacy of ESWT in adhesive capsulitis remains limited and heterogeneous. While some studies have reported reductions in pain and improvements in range of motion, uncertainties persist regarding the magnitude of clinical benefit, long-term outcomes, and potential to reduce recurrence. In addition, heterogeneity in ESWT protocols – including wave type (focal vs. radial), energy levels, number of sessions, and concomitant therapies – complicates comparisons across studies and limits generalizability [8–10].

In this context, identifying clinical factors as predictors of recurrence may aid in optimizing patient selection for ESWT and improving treatment outcomes. Potential risk factors include symptom duration, presence of metabolic comorbidities, and the disease stage at the time of intervention [10-14].

The aim of this study is to evaluate the effectiveness of ESWT in promoting functional recovery in patients with adhesive capsulitis and to analyze clinical factors associated with recurrence, with the goal of contributing to the development of more effective and personalized therapeutic strategies for this condition. In addition, a better understanding of the mechanisms underlying the response to ESWT could provide a foundation for future studies aimed to enhance its clinical applicability [11,12,15–17].

## Materials and Methods

## Study design

A retrospective observational study was conducted on a cohort of 19 patients with a confirmed diagnosis of adhesive capsulitis of the shoulder, treated with ESWT at a specialized center for musculoskeletal disorders. Diagnosis was established based on clinical criteria and

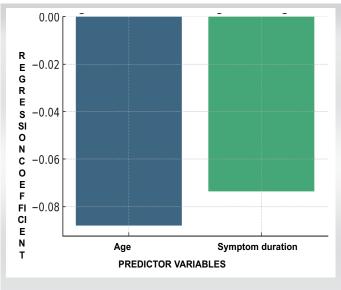


Figure 3: Logistic regression analysis of predictors of recurrence.

imaging findings, with magnetic resonance imaging (MRI) or ultrasonography used to rule out associated pathologies, such as rotator cuff tears or significant bursitis.

#### Inclusion and exclusion criteria

## Inclusion criteria

- $\bullet$  Age >18 years with clinical and imaging-based diagnosis of adhesive capsulitis
- Inflammatory or adhesive stage of the disease
- Persistence of symptoms for at least 3 months without improvement following conventional treatment
- Persistence of symptoms for at least 3 months without improvement following prior conventional treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and physical therapy
- $\bullet \, Signed\, informed\, consent.$

## **Exclusion criteria**

- Prior surgery on the affected shoulder
- Presence of inflammatory arthritis, joint infection, or concomitant neuromuscular disorders
- $\bullet \, Full-thickness\, rotator\, cuff\, tear$
- Use of anticoagulant therapy contraindicating ESWT
- History of active malignancy or decompensated systemic disease
- Use or recent exposure to quinolones, isotretinoin, NSAIDs, or corticosteroids.

## Studyhypotheses

- Primary hypothesis: ESWT improves shoulder function and reduces pain in patients with adhesive capsulitis compared to baseline pretreatment.
- Secondary hypothesis: The phase of capsulitis, symptom duration, and the presence of metabolic comorbidities influence the likelihood of recurrence 1 year after ESWT.

## **Analyzed variables**

The variables included in the analysis were classified into four main

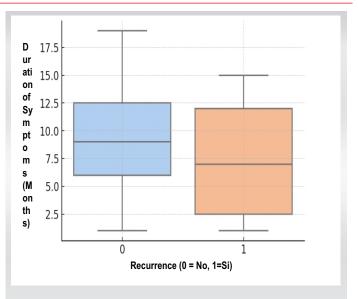


Figure 4: Association between disease duration and risk of recurrence.

categories:

## **Demographic variables**

- Age (expressed as mean ± standard deviation)
- Sex (male/female).

#### Clinical variables

- Disease phase at the time of treatment (freezing, frozen, or thawing).
- Time from symptom onset to initiation of ESWT (in weeks).
- Presence of metabolic comorbidities (diabetes mellitus, hypothyroidism, dyslipidemia)
- Previous use of conservative treatments (corticosteroid injections, physical therapy, analgesics).

#### Treatment variables

- Total number of ESWT sessions administered
- Type of wave applied (focal or radial)
- Applied energy intensity (mJ/mm<sup>2</sup>) and frequency (Hz)
- Total cost of treatment.

## **Functional outcomes**

- $\bullet$  Functional status was assessed using the DASH score, recorded at baseline and 3 months after the final ESWT session
- Clinical improvement was defined as a reduction of  $\geq\!10$  points on the DASH scale
- Pain intensity was evaluated using the visual analog scale (VAS) before and after treatment.

## Recurrence

• Recurrence was defined as the reappearance of pain and significant functional limitation requiring additional interventions within the 1st year following treatment.

## Shock wave therapy protocol in patients

The therapeutic protocol consisted of 3–4 sessions of ESWT, with 1-week interval between sessions. The procedure was performed by an

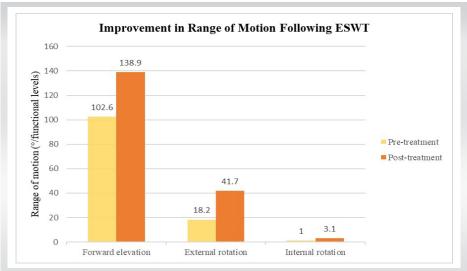


Figure 5: Comparison of shoulder range of motion before and after extracorporeal shockwave therapy (ESWT). A significant improvement was observed in anterior elevation, external rotation, and functional internal rotation following treatment. Anterior elevation increased from  $102.6^{\circ}$  to  $138.9^{\circ}$ , external rotation from  $18.2^{\circ}$  to  $41.7^{\circ}$ , and internal rotation (assessed by functional level) improved by an average of 2.1 levels. These findings support the beneficial effect of ESWT on joint mobility in patients with adhesive capsulitis.

orthopedic and trauma surgeon, certified in the clinical use of ESWT. Local anesthesia was not used; basic analgesia was provided with paracetamol and lidocaine patches, ensuring the preservation of the physiological pain threshold during therapy. The patient was positioned in the lateral decubitus position, with the affected shoulder exposed, the elbow extended, and a cervical support to ensure comfort throughout the procedure.

The first phase involved the application of Radial Extracorporeal Shock Wave Therapy (R-ESWT) using a BTL-6000 RSWT Elite device, following a progressive protocol starting at 1.5 bar pressure and 7 Hz frequency, distributing approximately 3,000 impulses across the anterior, lateral, and posterior shoulder regions, including the trapezius (see Image 1). The intensity was gradually increased to 3–4 bar according to individual tolerance.

Immediately following this, the second phase was initiated using Focused Extracorporeal Shock Wave Therapy (F-ESWT) applied with a BTL-6000 FSWT device guided by ultrasound (see Image 2). The



Image 1: First phase: Radial pressure waves.

penetration depth was adjusted according to the patient's anatomy. Initial energy was set at 0.08 mJ/mm2 increasing maximum energy levels up to 0.20 mJ/mm2 with a frequency of 3–4 Hz, delivering 1,500–2,000 focal impulses, carefully avoiding thoracic areas to minimize the risk of pulmonary injury.

The final phase aimed to provide a sedative effect, using the R-ESWT at 15 Hz and 1.5 bar, delivering approximately 1,500 total impulses around the shoulder perimeter (see Image 3). Following each session, the patient was instructed to perform stretching exercises and passive mobilization to tolerance. The use of NSAIDs or corticosteroids was contraindicated during the treatment course. Continuous clinical evaluations were performed at each session, assessing joint range of motion, pain intensity, and shoulder function.

Upon completion of the ESWT protocol, the patient was prescribed a 10-session assisted

physical therapy regimen to consolidate functional gains and optimize joint mobility. In addition, systematic clinical monitoring of comorbidities was maintained to assess their potential impact on the progression of adhesive capsulitis.

## Statistical analysis

Data analysis was performed using R statistical software (version 4.2.1). The normality of quantitative variables was assessed using the Shapiro–Wilk test. Pre- and post-treatment DASH scores were compared using the paired Student's t-test for normally distributed data or the Wilcoxon signed-rank test for non-normal distributions. A multivariable logistic regression analysis with Lasso regularization was conducted to identify independent predictors of recurrence. Candidate variables included age, sex, disease stage, symptom duration, comorbidities, and number of ESWT sessions. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated.

A P < 0.05 was considered statistically significant for all tests. In addition, the correlation between functional improvement and the number of ESWT sessions was evaluated using Spearman's rank correlation coefficient.

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and approved by the institutional ethics committee. Informed consent was obtained from all participants before inclusion in the study.

## Results

## Effectiveness of treatment

Analysis of the DASH scale demonstrated a significant improvement in shoulder function following treatment with ESWT. The mean pretreatment score was 62.4  $\pm$  11.2, while the post-treatment score at 3 months was 35.6  $\pm$  9.8, demonstrating a statistically significant difference (P < 0.001) according to the paired Student's t-test. Spearman's correlation analysis did not reveal a significant relationship





Image 2: Second phase: Focused shock waves applied guided by ultrasound.

between the number of ESWT sessions and functional improvement (r = 0.12, P = 0.34), suggesting that the clinical benefit is not directly dependent on the number of sessions administered. A significant reduction in pain intensity was also observed, as measured by the VAS, with a mean decrease of 3.8 points following treatment (P < 0.001), confirming the effectiveness of ESWT in pain modulation. Functional improvement and pain reduction over time are illustrated in Figures 1 and 2 (see Figure 1 and Figure 2).

## Predictive factors for recurrence

Clinical factors influencing the likelihood of recurrence at 1-year follow-up were identified. The overall recurrence rate was 26.3% (5 out of 19 patients).

Logistic regression analysis with Lasso regularization revealed the following:

• Age had a positive effect on the likelihood of recurrence (OR = 1.08; 95% CI: 1.01-1.15; P = 0.02), indicating that each additional year of age increases the risk of recurrence.



Image 3: Third phase: sedative effect, using theradial pressure waves.

- Longer symptom duration before treatment was significantly associated with a higher risk of recurrence (OR = 1.23; 95% CI: 1.06–1.41; P = 0.004), suggesting that delays in intervention reduce the long-term effectiveness of ESWT.
- Treatment cost had a slight protective effect against recurrence (OR = 0.92; 95% CI: 0.85-0.99; P = 0.048), possibly related to access to complementary therapies, such as physiotherapy or intra-

articular injections.

Figures 3 and 4 illustrate these findings (see Figure 3 and Figure 4) Improvement in functionality and pain relief was accompanied by a significant recovery in the range of joint mobility among patients treated with ESWT.

Specifically, active anterior shoulder elevation increased on average from  $102.6^{\circ} \pm 14.3^{\circ}$  at baseline to  $138.9^{\circ} \pm 10.7^{\circ}$  at 3 months post-treatment (P < 0.001). External rotation at 90° abduction improved from  $18.2^{\circ} \pm 9.4^{\circ}$  to  $41.7^{\circ} \pm 8.6^{\circ}$  (P < 0.001), while internal rotation (assessed as the highest vertebral level reached behind the back) improved by an average of 2.1 levels on the functional scale (e.g., from the sacral region to the T12 level).

This recovery was more pronounced in patients in the inflammatory phase compared to those in the adhesive phase, suggesting greater capsular plasticity in earlier stages of the disease. The gain in mobility was moderately correlated with a reduction in VAS pain scores (r = -0.46, P=0.03), supporting the hypothesis that the analgesic effect of ESWT facilitates more active and effective mobilization (see Figure 5). Furthermore, the progressive reintroduction of assisted exercises and physiotherapy following completion of the shockwave protocol may have contributed to consolidating these functional improvements, reflecting a synergistic approach between biological treatment and targeted rehabilitation.

## Hypothesis testing

- Primary hypothesis: The hypothesis that ESWT improves functionality and reduces pain in patients with adhesive capsulitis was confirmed, as evidenced by a significant post-treatment decrease in both DASH and VAS scores.
- Secondary hypothesis: This hypothesis was partially validated. Clinical factors, such as age and disease duration emerged as significant predictors of recurrence. However, the influence of metabolic comorbidities did not reach statistical significance in the multivariate model (P > 0.05).

These findings suggest that early intervention with ESWT in younger patients may optimize functional outcomes and reduce the risk of recurrence.

#### Discussion

Our findings confirm that ESWT significantly improves function and reduces pain in patients with adhesive capsulitis. However, the likelihood of recurrence appears to be influenced by clinical factors, such as patient age and delays in initiating treatment. These results underscore the importance of early intervention to optimize functional outcomes and minimize the risk of disease recurrence.

## Comparison with previous studies

Our findings align with existing literature demonstrating the efficacy of ESWT in improving joint function and alleviating pain in musculoskeletal disorders. A recent study by Huang et al. [18] reported significant improvements in range of motion and pain reduction in patients with adhesive capsulitis treated with ESWT, yielding results comparable to those observed in our cohort. However, a key difference lies in the treatment protocol: while our study employed a fixed number of sessions, the aforementioned study

identified a dose-dependent response, with a higher number of ESWT sessions correlating with more rapid and sustained clinical improvement [5,13,14,18–21].

In our study, a mean reduction of 26.8 points was observed on the DASH scale, which is comparable to the findings reported by Farhat et al., [22] who noted a 27-point decrease in patients with adhesive capsulitis treated with ESWT combined with intensive physiotherapy. Similarly, the 3.8-point reduction in VAS scores recorded in our cohort aligns with the 3.5–4.2-point decrease reported in previous studies utilizing similar energy and frequency protocols. These data strengthen the robustness of our findings and suggest that the applied protocol – which incorporates sequential phases of radial, focused, and sedative shockwaves – may offer a therapeutic advantage over monophasic regimens or those lacking ultrasound guidance [5,13,14,19–21].

A distinctive strength of our study lies in the progressive, multimodal structure of the ESWT protocol employed. The integration of an initial phase of radial shockwaves for tissue priming, followed by an ultrasound-guided focused phase for deep-targeted treatment, and a third neurophysiological modulation phase with sedative intent, enabled targeted and adaptive stimulation. This approach maximized patient tolerance while enhancing the analgesic and antifibrotic effects of the therapy. This therapeutic sequence has not been widely described in the present literature and may represent a reproducible model with broader applicability to other musculoskeletal disorders [5,13,14,19,21,22].

Other studies, such as that by Chen et al., [23] suggest that ESWT is particularly effective when combined with intensive physical therapy, which may account for the variability in outcomes reported across different investigations. In our study, we did not observe a significant relationship between the number of ESWT sessions and functional improvement, suggesting that the timing of intervention may be more critical than its intensity. This finding aligns with the study by Chen et al., [23] which concluded that early intervention with ESWT has a greater impact on functional recovery than the total number of sessions administered [14,16,17,23–26].

Furthermore, several studies have compared the efficacy of ESWT to conventional treatments, such as corticosteroid injections and intensive physiotherapy. These studies have shown that while ESWT demonstrates comparable short-term efficacy, it offers additional benefits in pain reduction and in preventing the progression of capsular fibrosis over the long term [16,17,27].

Regarding predictive factors of recurrence, our results are consistent with the findings of Ogden et al., [2,17] who identified age and duration of adhesive capsulitis as independent predictors of recurrence. This reinforces the notion that early diagnosis and timely therapeutic approach are essential for improving long-term outcomes [2,17].

## Pathophysiological mechanisms and clinical relevance

The mechanism of action of ESWT in adhesive capsulitis is based on its ability to modulate inflammation, promote neovascularization, and alter the cellular response in fibrotic tissues. Biomechanical studies have demonstrated that ESWT reduces the expression of growth factors associated with capsular fibrosis and improves the elasticity of

the capsular tissue. This may explain its positive effect on restoring mobility and relieving pain [4,26,28–31].

The lack of correlation between the number of ESWT sessions and functional improvement suggests that the therapeutic threshold of mechanical stimulation may be achieved with a limited number of sessions. This is consistent with findings in other musculoskeletal conditions, such as calcific tendinopathy and plantar fasciitis, where clinical benefit does not always correlate with the frequency of treatment [28-30].

#### **Study limitations**

Despite the clinical relevance of our findings, this study has several limitations that should be considered:

- 1. Small sample size: The cohort of 19 patients is relatively small, which limits the generalizability of the results to a broader population
- 2. Retrospective design: The retrospective nature of the study introduces the risk of selection and information bias, which may affect the validity of the findings
- 3. Lack of a control group: ESWT was not compared with other standard treatments, such as intensive physical therapy or intraarticular injections, limiting our ability to assess the relative superiority of ESWT
- 4. One-year follow-up: While a 12-month follow-up allows for assessment of early recurrence, it is insufficient to determine the long-term effects of ESWT in adhesive capsulitis
- 5. Variability in ESWT protocols: Differences in shockwave intensity, the type of shock wave used (focused vs. radial), and frequency of application may influence clinical outcomes and could potentially explain the heterogeneity observed across studies
- 6. Lack of objective measurement of capsular fibrosis: Although the DASH and VAS scales provide functional evaluation, future studies may benefit from the use of MRI or elastography to assess tissue changes induced by ESWT.

#### **Future directions**

To enhance understanding of the impact of ESWT on adhesive capsulitis and optimize its application in clinical practice, future research should consider the following aspects:

- Randomized prospective studies: Experimental designs with larger sample sizes would allow for confirmation of the efficacy of ESWT and its impact on long-term recurrence
- Comparison with other treatments: Assessing ESWT against other therapeutic options, such as intensive physical therapy, intra-articular corticosteroid injections, or hyaluronic acid, could help define its role within the treatment algorithm for adhesive capsulitis
- Optimization of the ESWT protocol: Studies are needed to evaluate the influence of energy intensity, wave type, and session frequency on clinical outcomes, to standardize the application of ESWT for this condition
- Subgroup analysis: Investigating the effectiveness of ESWT in specific populations, such as patients with metabolic comorbidities (e.g., diabetes mellitus, hypothyroidism) or those in different disease stages could enable more precise selection of ideal candidates for this therapy
- Long-term follow-up: Extending the follow-up period beyond 24

months would allow assessment of the durability of ESWT's therapeutic effects and its impact on patient quality of life

• Evaluation of therapeutic response biomarkers: Identifying biological or inflammatory markers that predict a better response to ESWT may improve patient selection and allow for more personalized treatment approaches.

#### Conclusion

Our study reinforces the utility of ESWT in the management of

adhesive capsulitis, highlighting its effectiveness in improving function and reducing pain. However, clinical factors, such as patient age and disease duration play a key role in the likelihood of recurrence. The implementation of early diagnostic strategies and optimization of treatment protocols could significantly improve outcomes in these patients. Looking ahead, rigorously controlled studies will be essential to definitively establish the role of ESWT in adhesive capsulitis and to define its applicability across different patient subgroups.

**Declaration of patient consent:** The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given the consent for his/ her images and other clinical information to be reported in the journal. The patient understands that his/ her names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Conflict of interest: Nil Source of support: None

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