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# Comparative Efficacy of Standardized and Randomized Shockwave Therapy in Adhesive Capsulitis: A Pilot Study

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***ABSTRACT***

***Background***

*Frozen shoulder or adhesive capsulitis is a musculoskeletal disorder with pain, stiffness, and limited range of motion (ROM). It highly impairs activities of daily living and quality of life. Extracorporeal Shockwave Therapy (ESWT) has been a potential non-surgical treatment option, but the best dosing protocol standardized vs. randomized is unclear. In this study, these two methods of ESWT will be compared in relieving pain and enhancing mobility.*

***Methods***

*A single-blind randomized controlled trial involving 30 patients was performed and divided into three groups: Group 1 (Standardized ESWT), Group 2 (Randomized ESWT), and Group 3 (Exercise-only control). Treatment was for four weeks with three sessions a week. Pain and functional outcomes were evaluated using the Shoulder Pain and Disability Index (SPADI), while ROM was evaluated using a goniometer. Observations were taken on Week 0, Week 2, Week 3, and Week 4, and statistical tests were conducted with $p < 0.05$ set as significant.*

***Results***

*Both randomized and standardized shockwave therapy significantly alleviated pain and enhanced ROM in comparison to the exercise group ($p < 0.001$). SPADI scores reduced more in Group 1 (39.4) than in Group 2 (41.1), indicating marginally better pain reduction with standardized therapy. ROM improvement was equal in both shockwave groups, with Group 2 having marginally improved flexibility.*

***Conclusion***

*This research substantiates that shockwave therapy is more effective than exercise alone for the treatment of adhesive capsulitis. Systematic ESWT gave superior pain relief, but randomized ESWT gave flexibility. Long-term effects and optimization of individualized treatment should be researched in the future.*

***Keywords:*** *Adhesive Capsulitis, Frozen Shoulder, Shockwave Therapy, Standardized vs. Randomized Dosimetry, Pain Management, Range of Motion Improvement,*

## Introduction

Shoulder pain and disability of mobility are two of the most prevalent musculoskeletal conditions, which impact significantly on one's functional status and quality of life on a daily basis. A number of shoulder disorders such as adhesive capsulitis (frozen shoulder), rotator cuff injury, and tendinopathies contribute to pain and limited motion(1). Adhesive capsulitis is a disabling process that involves pain, stiffness, and progressive impairment of active and passive range of motion of the glenohumeral joint. It is usually idiopathic but can be secondary to disease involving the entire system, for example, diabetes mellitus, thyroid disease, or postoperative immobilization. While there are several treatment options, from corticosteroid injections and physical therapy to surgery, the use of Extracorporeal Shock Wave Therapy (ESWT) in adhesive capsulitis is a relatively new area of research(2,3).

Shock wave therapy was first discovered in 1982 as a treatment for urological disorders, specifically kidney stones (lithotripsy). It has grown in application over time to manage other orthopedic and musculoskeletal conditions such as plantar fasciitis, epicondylitis of the lateral epicondyle, and calcific tendinitis of the shoulder(4). Shock waves are pulse acoustic waves with high energy, which have the ability to stimulate cellular function, enhance blood flow, and initiate tissue healing. Application of ESWT to shoulder pain has been promising, but ideal dosing parameters—low-energy or high-energy are still unknown(5).

The efficacy of ESWT in adhesive capsulitis is founded on its mechanical and biological actions. Mechanically, microtrauma occurs due to the shock waves, which provokes an inflammatory response that augments tissue regeneration(6). Biologically, ESWT induces release of growth factors, stimulates collagen production, induces neovascularization, and inhibits calcification of soft tissues. Together, these actions culminate in relief of pain, range of motion improvement, and restoration of function. But despite these encouraging mechanisms, the optimal dosimetry (shock wave energy, frequency, and number of pulses per session) is unknown, and outcomes vary(7).

Various investigations have tried to investigate the effect of varying energy levels within ESWT. Some have opined that the most likely source of enhanced pain relief and functional gain is high-energy shock waves (energy flux density >0.2 mJ/mm²), whereas others propose low-energy shock waves (0.08–0.2 mJ/mm²), as they perceive them to be safer, less painful, and equally effective in some conditions. Given these conflicting views, a comparative study between high-energy and low-energy ESWT in adhesive capsulitis patients needs to be undertaken to identify the best treatment protocol(8,9).

Adhesive capsulitis occurs in about 2%–5% of the population worldwide, with a prevalence mostly in the 40–60 years age group. Perimenopausal women and people with diabetes or metabolic syndrome are at higher risk for adhesive capsulitis(10). Disease condition goes through three phases—freezing, frozen, and thawing that take months to years. Prodigious pain and increasing stiffness in freezing phase, constant stiffness but minimal pain in frozen phase, thawing phase suggests gradually improving movement. Adhesive capsulitis as a chronic disease requires proper timely management so as not to incapacitate the individual(11,12).

In spite of numerous treatment modalities, a gold-standard treatment is yet to be found. Physical therapy and manual mobilization are generally advised as first-line treatments, but their effectiveness is stage-specific(13). Intra-articular corticosteroid injections are useful for short-term pain relief but do not treat the underlying pathology. Surgical procedures, like arthroscopic capsular release or manipulation under anesthesia, are reserved for recalcitrant cases but are fraught with complications(14).

Extracorporeal Shock Wave Therapy (ESWT) is a non-surgical option, and it seems to be a promising step in relieving pain, decreasing stiffness, and improving range of motion in adhesive capsulitis patients(15). The optimal dosing schedule does not have agreement, though. There is evidence favouring high-energy ESWT because of its increased penetration and greater biological effects, but others propose the use of low-energy ESWT with equal efficacy and less side effects. In light of such uncertainty, an urgent need is to contrast the effectiveness of the two dosimetry protocols for adhesive capsulitis and mobility impairment treatment.

## Methodology

The study used a single-blind randomized controlled trial to contrast the impact of standardized shockwave therapy, randomized shockwave therapy, and an exercise-only program in patients with adhesive capsulitis (frozen shoulder). The aim was to identify the most effective treatment for pain alleviation and enhancement of range of motion (ROM). Participants were recruited according to predetermined inclusion and exclusion criteria and randomly allocated into one of three intervention groups. The research was carried out in a clinical setting that was controlled, thereby providing standardized procedures for data collection, treatment administration, and analysis.

30 participants were recruited in the pilot study, equally distributed in three groups: Group 1 (Standardized Shockwave Therapy, n=10), Group 2 (Randomized Shockwave Therapy, n=10), and Group 3 (Exercise-Only, n=10). The inclusion criteria had to meet age (40-60 years), adhesive capsulitis diagnosis, as well as severe shoulder pain and restriction of mobility. Exclusionary criteria were prior shoulder surgeries, corticosteroid injections in the previous three months, neurological conditions, or contraindications to shockwave treatment. Informed consent was obtained from all participants prior to recruitment.

Group 1 participants were administered standardized extracorporeal shockwave therapy (ESWT) with a preset energy flux density and frequency as per manufacturer instructions. Group 2 participants, on the other hand, received randomized shockwave therapy with varying energy intensity and frequency tailored individually according to response and tolerance in patients. Each group was given 12 sessions within four weeks, with therapy given three times a week. Shockwave therapy was administered with a radial shockwave device, treating the involved shoulder area. Each treatment session took about 15-20 minutes and was supplemented by a standardized strengthening exercise regimen.

The members of Group 3 (Exercise-Only) received no shockwave therapy but were placed on an exercise regimen that was aimed at enhancing mobility in the shoulder and decreasing stiffness. The exercise protocol consisted of passive stretching, active-assisted mobilization, and strengthening of the shoulder girdle. Exercises were carried out under supervision by a physiotherapist three times a week for four weeks to maintain intervention consistency.

To measure the efficiency of every intervention, data on baseline (Week 0), Week 2, Week 3, and Week 4 were collected. The main result measure was the Shoulder Pain and Disability Index (SPADI) that measures intensity of pain as well as functioning limitations. Second outcomes were ranges of motion measurements for adduction, abduction, flexion, extension, internal rotation, and external rotation tested with a goniometer. Pain levels were also measured on the Visual Analog Scale (VAS).

**Results**

**Table 1: Baseline Characteristics of Participants (Age, Weight, and Height)**

| | GROUP | N | Mean | Std. Deviation | P VALUE |
|---|---|---|---|---|---|
| AGE | 1 | 10 | 50.4 | 4.326 | 0.896 |
| | 2 | 10 | 51.5 | 6.485 | |
| | 3 | 10 | 51.1 | 4.886 | |
| | Total | 30 | 51 | 5.146 | |
| WEIGHT | 1 | 10 | 64 | 10.477 | |
| | 2 | 10 | 67.9 | 9.219 | 0.645 |
| | 3 | 10 | 64.9 | 9.243 | |
| | Total | 30 | 65.6 | 9.478 | |
| HEIGHT | 1 | 10 | 168.8 | 13.637 | 0.896 |
| | 2 | 10 | 168.2 | 10.337 | |
| | 3 | 10 | 168 | 10.296 | |
| | Total | 30 | 168.33 | 11.13 | |

GROUP 1 - standardized shockwave ratio, GROUP 2- randomized ratio, GROUP 3 – Exercises

Comparative analysis of the three groups - GROUP 1 with a normal shockwave ratio, GROUP 2 with a randomized ratio, and GROUP 3 with exercise interventions - yielded comparable baseline characteristics in terms of age, weight, and height. For age, the mean scores for GROUP 1, GROUP 2, and GROUP 3 were 50.4, 51.5, and 51.1, respectively, and the grand mean age was 51. The standard deviations ranged from 4.326 to 6.485, indicating a small spread. Statistical analysis showed that there were no differences in age between the groups ($p = 0.896$). Similarly, weight analysis revealed mean values of 64, 67.9, and 64.9 for GROUP 1, GROUP 2, and GROUP 3, respectively, with a total mean weight of 65.6. The standard deviations ranged from 9.219 to 10.477, and statistical analysis indicated no significant weight differences between the groups ($p = 0.645$). For height, mean heights for GROUP 1, GROUP 2, and GROUP 3 were 168.8, 168.2, and 168, respectively, with an overall mean height of 168.33. Standard deviations ranged from 10.296 to 13.637, and the statistical analysis revealed no significant difference in height between the groups ($p = 0.896$). Overall, these results present an evenly distributed mix of demographic characteristics among the three groups that set the stage for a solid comparative analysis of the follow-up interventions.

**Table 2**: SPADI Scores for All Groups

| | **GROUP** | **Mean** | **Std. Deviation** | **P VALUE** |
|---|---|---|---|---|
| **SPADI WEEK 0** | 1 | 87.6 | 6.947 | 0.194 |
| | 2 | 81.4 | 9.606 | |
| | 3 | 86.6 | 7.058 | |
| | Total | 85.2 | 8.168 | |
| **SPADI WEEK 2** | 1 | 77.9 | 13.127 | 0.249 |
| | 2 | 75.5 | 12.14 | |
| | 3 | 68.7 | 12.129 | |
| | Total | 74.03 | 12.672 | |
| **SPADI WEEK 3** | 1 | 59.8 | 6.088 | 0.001 |
| | 2 | 59.9 | 6.935 | |
| | 3 | 72.5 | 14.409 | |
| | Total | 64.07 | 11.298 | |
| **SPADI WEEK 4** | 1 | 39.4 | 6.004 | <0.001 |
| | 2 | 41.1 | 4.557 | |
| | 3 | 78.9 | 15.716 | |
| | Total | 53.13 | 20.933 | |

GROUP 1 - standardized shockwave ratio, GROUP 2- randomized ratio, GROUP 3 – Exercises

The dynamic trends in the levels of shoulder pain and disability at four time points (Weeks 0, 2, 3, and 4) across three intervention groups (GROUP 1 - ratio standardized shockwave, GROUP 2 - ratio randomized, GROUP 3 - Exercises) were observed through analysis of Shoulder Pain and Disability Index (SPADI) scores. At baseline (Week 0), the groups' mean SPADI scores were 87.6 for GROUP 1, 81.4 for GROUP 2, and 86.6 for GROUP 3, with an overall mean of 85.2. No statistically significant group differences were found at Week 0 ($p = 0.194$). With continuation of the intervention into Week 2, mean SPADI scores across all groups reduced (77.9 in GROUP 1, 75.5 in GROUP 2, and 68.7 in GROUP 3), indicating recovery from shoulder pain and disability. Differences, however, were not statistically significant at this time ($p = 0.249$). There was a statistically significant and evident drop in SPADI scores at Week 3 with mean scores of 59.8 in GROUP 1, 59.9 in GROUP 2, and 72.5 in GROUP 3 for a total overall mean of 64.07 ($p = 0.001$). The trend continued through Week 4, when significant drops in mean SPADI scores in GROUP 1 (39.4) and GROUP 2 (41.1) and an unexpected increase in GROUP 3 (78.9) were observed. The grand mean during Week 4 was 53.13, and group differences were very significant ($p < 0.001$). These findings suggest that the interventions, particularly standardized shockwave and randomized ratios, significantly decreased shoulder pain and disability, which shows the potential impact of these measures in managing and promoting the well-being of patients with shoulder conditions.

**TABLE NO 3 - Pre-Post Intervention Range of Motion of Shoulder**

| Movement | Group 1 Pre (Mean ± SD) | Group 2 Pre (Mean ± SD) | Group 3 Pre (Mean ± SD) | P-Value Pre | Group 1 Post (Mean ± SD) | Group 2 Post (Mean ± SD) | Group 3 Post (Mean ± SD) | P-Value Post |
|---|---|---|---|---|---|---|---|---|
| Adduction | 80.1 ± 5.705 | 80.3 ± 5.755 | 81.9 ± 6.173 | 0.757 | 99.1 ± 14.279 | 89.6 ± 15.02 | 86.0 ± 3.559 | 0.061 |
| Abduction | 79.4 ± 7.471 | 79.7 ± 4.423 | 78.9 ± 6.983 | 0.961 | 93.3 ± 14.299 | 96.9 ± 12.653 | 88.5 ± 5.662 | 0.278 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Flexion | 82.6 ± 4.789 | 78.4 ± 8.017 | 79.1 ± 6.624 | 0.329 | 102.2 ± 8.311 | 102.4 ± 9.823 | 81.8 ± 6.033 | <0.001 |
| Extension | 15.0 ± 3.432 | 14.6 ± 3.502 | 15.6 ± 3.864 | 0.824 | 26.6 ± 4.648 | 27.8 ± 4.417 | 15.5 ± 3.567 | <0.001 |
| Internal Rotation | 21.1 ± 5.547 | 19.6 ± 4.061 | 19.2 ± 4.517 | 0.646 | 43.9 ± 3.381 | 45.7 ± 2.359 | 21.1 ± 7.593 | <0.001 |
| External Rotation | 19.4 ± 6.45 | 20.8 ± 4.077 | 21.4 ± 5.42 | 0.745 | 45.7 ± 3.302 | 43.5 ± 2.415 | 19.9 ± 5.744 | <0.001 |

All three groups had similar baseline ROM values before the intervention, and this made all participants have similar shoulder mobility at the onset. In terms of adduction, the pre-intervention mean values for Group 1 (standardized shockwave), Group 2 (randomized shockwave), and Group 3 (exercise-only) were 80.1°, 80.3°, and 81.9°, respectively. Comparable trends were also seen for the other movements, including abduction (mean values of 79.4°, 79.7°, and 78.9° for the respective groups), flexion (82.6°, 78.4°, 79.1°), and extension (15.0°, 14.6°, 15.6°). The internal and external rotation measurements were also reasonably comparable between groups, with no statistically significant differences ($p > 0.05$) at the start of the study. These findings indicate that each of the three intervention groups was starting from an equivalent baseline, allowing for similar comparisons.

Following the intervention period, significant ROM gains were noted in shockwave-treated groups (Groups 1 and 2) compared with the exercise-alone group (Group 3). For adduction, post-treatment mean values increased to 99.1° for Group 1, 89.6° for Group 2, and 86.0° for Group 3. Although differences between Groups 1 and 2 were not statistically significant ($p = 0.061$), both improved more than the exercise-only group. The same pattern was seen for abduction, in which Group 1 averaged 93.3° post-treatment, Group 2 averaged 96.9°, and Group 3 averaged lower at 88.5° ($p = 0.278$).

The greatest improvements occurred in flexion, extension, and rotation motion. In flexion, both Group 1 and Group 2 had a mean post-treatment score of 102.2° and 102.4°, respectively, against just 81.8° for Group 3 ($p < 0.001$). Similarly, on extension, both Groups 1 and 2 had significantly increased mobility with a post-treatment mean of 26.6° and 27.8°, respectively, against only 15.5° in the exercise group ($p < 0.001$). The same pattern was noted in internal and external rotation, with both shockwave therapy groups demonstrating higher improvements, while the exercise-alone group demonstrated no changes ($p < 0.001$ for both measures).

## Discussion

This study aimed to determine whether randomized or standardized shockwave therapy was superior for the management of adhesive capsulitis with reference to pain reduction and range of motion (ROM) improvement. Results indicate that both randomized and standardized shockwave therapy were significantly superior to exercise-only intervention but with subtle differences among the two shockwave therapies. The Shoulder Pain and Disability Index (SPADI) scores reported that standardized (Group 1) and randomized (Group 2) shockwave therapy each had a significant reduction in pain, whereas the exercise-alone group (Group 3) showed minimal improvement and even a rise in SPADI scores at Week 4. The three groups were comparable in SPADI scores at Week 0, and this made the groups equivalent in baseline pain prior to intervention. By Week 2, the SPADI scores had decreased somewhat for all groups but were not yet statistically significantly different ($p = 0.249$), which meant that intervention effects were only beginning to emerge. But by Week 3, there was a significant divergence. At Week 3, both randomized (59.9) and standardized (59.8) shockwave therapy groups were significantly lower on SPADI scores than the exercise-alone group (72.5), thereby confirming that shockwave therapy was better than exercise alone ($p = 0.001$). The trend continued in Week 4, where shockwave therapy with standardization and randomization once again reduced pain scores to 39.4 and 41.1, respectively, whereas the exercise-only group exhibited a surprising increase to 78.9 ($p < 0.001$). This suggests that shockwave therapy not only provided greater relief from pain but also gave enduring improvements in the long term, whereas exercise alone could not give consistent pain reduction.

Although both the randomized and standardized shockwave therapy were highly effective, the data suggests that the standardized therapy could be marginally better. The Week 4 SPADI score in the standardized group was slightly less than in the randomized group, which is 39.4 compared to 41.1, showing marginally better pain relief. Although small, this difference suggests that a fixed, manufacturer-determined shockwave dose could be more predictable and reliable than a patient-adjusted dose. When the Range of Motion (ROM) improvements were examined, the same pattern was observed. All three groups had comparable baseline ROM measurements before treatment, and there were no statistically significant differences. However, with the treatment given for four weeks, standardized and randomized shockwave therapy groups had significant increases in all movement parameters, whereas exercise alone had minor gains. During flexion, standardized (102.2°) and randomized (102.4°) shockwave therapy groups both improved significantly more than the exercise-only group (81.8°) ($p < 0.001$). During extension, the standardized group was 26.6° post-intervention, slightly less than the 27.8° of the randomized group, but both were significantly higher than the exercise group (15.5°) ($p < 0.001$). Internal and external rotation also significantly improved in the two shockwave therapy groups, with no difference between them.

Although the ROM data suggest that the standardized and randomized shockwave treatments were both successful, neither strategy was clearly better in all variables. The group treated with a standardized approach yielded slightly greater outcomes in SPADI pain relief, whereas the group treated with randomized treatment yielded more modest ROM increases in some, but not all, movements such as extension. These differences, however, were small, and both strategies proved extremely effective for the return of function and for pain relief against exercise alone.

The clinical significance of the results is that shockwave therapy should be the first-line treatment for adhesive capsulitis since it is superior to exercise alone in pain reduction and functional recovery. Of the two dosing regimens, standardized shockwave therapy is slightly more effective in pain reduction, but randomized dosing provides more flexibility in adjusting the treatment according to patient response. This suggests that clinicians would want a standard treatment for more consistent outcomes, but randomized treatment might still benefit patient-specific adaptation.

## Conclusion

This research finds that shockwave therapy is much more effective than exercise alone in the treatment of adhesive capsulitis. Standardized and randomized shockwave therapy protocols both resulted in significant reduction of pain and improvement in ROM, but the standardized protocol showed slightly lower reductions in pain levels, which would indicate that using a fixed-dose protocol could provide more predictable outcomes. Yet the randomized method still brought about similar ROM gains, which would show that both procedures can be optimally applied in clinical practice. Based on these results, standardized shockwave therapy would be the preferred method when pain relief is given the highest priority, and randomized therapy is still an option for individualized treatment according to patient requirements. Long-term results, patient-specific response to therapy, and the best combination of shockwave therapy with exercise to achieve optimal patient recovery are areas that need to be addressed in future studies.

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