Original Article

Efficacy of Low-level Laser Versus High-intensity Laser Therapy in the Management of Adhesive Capsulitis: A Randomized Clinical Trial

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Abstract

Background: Low-level laser therapy (LLLT) and high-intensity laser therapy (HILT) are effective in alleviating pain and improving functionality in patients with adhesive capsulitis (AC); however, no study has compared the efficacy of these two laser treatments.

Objective: To compare the effectiveness of LLLT and HILT in improving the shoulder joint range of motion and functional status and in reducing pain level in patients with AC.

Trial Design: Prospective, randomized, parallel group, patient- and assessor-blinded.

Methods: A total of 45 patients (aged: 18–65 years) with complaint of shoulder pain were evaluated for inclusion criteria, which included being aged 18–65 years and a diagnosis of AC based on physical examinations. Using computer-generated random numbers, eligible patients were randomized into two groups: HILT + stretching exercise and LLLT + stretching exercise groups. Both HILT and LLLT were performed three times/week for 3 weeks. Functional status and pain of the patients were evaluated with Shoulder Pain and Disability Index (SPADI) and Visual Analog Scale (VAS), while shoulder joint range of motion was measured with goniometry. All assessments were done before and 3 weeks after treatment.

Results: A total of 40 patients (20 in each group) completed the study. At baseline, there was no statistically significant difference in the demographic and clinical characteristics between both groups. Both the LLLT and HILT groups showed significant improvement in the VAS and SPADI scores 3 weeks after treatment; however, the improvement was significantly higher in the HILT group than the LLLT group. There was no significant improvement in goniometric scores in both groups compared with baseline. No injury or other musculoskeletal complications were recorded during or after the treatments.

Conclusion: HILT + stretching exercise treatment was more effective than LLLT + stretching exercise for improving functional parameters and pain in patients with AC.

Trial Registration: ClinicalTrials.gov Identifier: NCT05469672.

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Keywords: Adhesive capsulitis, functional status, high-intensity laser therapy, low-level laser therapy, pain, range of motion

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INTRODUCTION

Adhesive capsulitis (AC) is characterized by painful progressive loss of passive and active shoulder range of motion. It affects 2% to 5% of the general population and most commonly women aged 40–60 years.[1] Thyroid dysfunction, chronic liver disease, rotator cuff tendinopathy, biceps tendinopathy, breast or cervical spine surgery, and neurological disorders are risk factors for AC.[1,2] Although it has been reported to be self-limiting, it usually resolves within 2 to 3 years. However, studies have also reported that in about 40% of patients, stiffness and pain persist beyond 3 years.[3]

Physiotherapy and rehabilitation are of significant importance in AC due to varying degrees of pain, limitation of movement, and functional losses in the joint. In the clinical treatment of shoulder problems, conservative therapy methods such as oral non-steroidal anti-inflammatory drugs, steroid injections, ultrasonography-guided hydrodilatation,[2,4] electrotherapy, hot applications, ultrasound, massage and manipulation[4,5] are used; stretching and strengthening exercises and mobilization techniques are the most commonly used methods to increase the range of motion of the joint, reduce pain, and strengthen the muscles around the joint.[2,4,5]

Another method of treating AC is low-level laser therapy (LLLT). LLLT reduces pain and improves function in patients with AC.[4] Nowadays, the pulsed neodymium-doped yttrium aluminum garnet (Nd: YAG) laser, a form of high-intensity laser therapy (HILT), is being used as another treatment modality. HILT can stimulate and reach deeper and wider areas of the fascia. Moreover, significantly greater amounts of energy can be transferred to the tissue during a HILT session compared with LLLT.[6] The photochemical and photothermic effects of HILT may simulate collagen production within tendons and increase blood flow, vascular permeability, and have an anti-inflammatory effect.[7,8] Thus, HILT may help to repair damaged tissue and remove the pain stimulus. HILT has been shown to reduce pain and improve functions in patients with AC.[9]

To the best of our knowledge, no clinical studies have compared the efficacy of LLLT and HILT in the management of AC. Such findings would help in determining the optimal treatment modality. Thus, the aim of this study was to compare the efficacy of LLLT and HILT for the treatment of AC.

METHODS

Trial design, setting, and participants

This prospective, randomized, parallel group, patient- and assessor-blinded clinical trial with 3-week treatment and follow-up periods was conducted between September 2022 and October 2022 in the Department of Physical Medicine and Rehabilitation, Necmettin Erbakan University. The study was approved by the Research Ethics Committee, Faculty of Medicine, The Necmettin Erbakan University, Konya, Turkey.

A total of 45 patients who presented to the University's hospital with complaint of shoulder pain were evaluated for inclusion in the study. Patients were included in the study if they (1) were aged 18–65 years, (2) had been diagnosed with AC, characterized by limitation of passive external rotation of the affected shoulder to <50% of the contralateral shoulder[9] and normal radiographic finding of the affected shoulder, (3) had severe pain and shoulder limitation for at least 3 months, and (4) were literate and able to understand verbal instructions in Turkish as well as provide written consent for participation. Patients were excluded if they had (1) calcific tendinopathy, glenohumeral osteoarthritis, fracture, shoulder trauma, undergone shoulder surgery, history of malignancy and infection, history of inflammatory rheumatic diseases; (2) bilateral simultaneous AC; (3) recent history of breast, lung, or bypass surgery/radiotherapy; (4) corticosteroid injection to the same shoulder in the past 1 year; (5) brachial plexus lesion/cervical radiculopathy; (6) neuromuscular disease history; and (7) physical therapy for the same shoulder in the past 6 months.

Sample size

Sample size was determined using the G-Power 3.1 software.[10] Power analysis showed that 20 participants were needed for each group, with 80% power and 5% type 1 error. The effect size was 1.645, based on the VAS scores for pain severity as the primary outcome.[11]

Randomization and blinding

All enrolled patients were randomly divided into either of the two treatment groups in a 1:1 ratio. The study used block and stratified randomization. All patients were enrolled in the study by the specialist medical doctor. Concealed allocation of the participants was performed using a computer-generated randomized table of numbers generated by an independent person before the initiation of the study. Numbered cards with the random assignment and containing information about the group allocation were prepared in opaque, sealed envelopes by the same

independent person. The physiotherapist opened the envelope and applied the treatment program according to the group.

According to the study design, the specialist medical doctor who evaluated and followed the patients (data collector) and the patients were blinded to the treatment groups and study design. Only the physical therapist administering the treatment was aware of the treatment group to which patients were allocated.

Interventions

High-intensity laser therapy

A BTL-6000 high-intensity laser was used for HILT (BTL-6000 high-intensity laser 12 W, Stevenage, Hertfordshire, UK). A hot laser derived from a Nd: YAG laser has 12 W and 1064 nm characteristics. The device was administered to the shoulder area in two steps in the HILT group: phase I and phase II. The administration was made using continuous circular movements in both phases I and II. The first three sessions consisted of a 75-second intermittent phase analgesic effect at 8 W and 10 J/cm^2 for a total energy of 100 J. The following six sessions consisted of a continuous 30-second bio-stimulating effect with a dosage of 12 W 120 J/cm^2. The scanning was performed parallel to the joint line, with the arm of the patient positioned in internal rotation on the posterior scan and external rotation on the anterior scan. A total of eight points were irradiated along the glenohumeral joint. Over the course of 3 weeks, nine treatment sessions of HILT were given.

Low-level laser therapy

For LLLT, laser treatment was applied using gallium–aluminum–arsenide infrared diode laser (Chattanooga, Mexico, USA) at a wavelength of 904 nm, a frequency of 5000 Hz and output power of 240 Mw. The spot area is about 0.5 cm^2. A total of 9 points were irradiated along the glenohumeral joint, with a power intensity of 3 J/cm^2 at each point. The application time was 50 seconds for each point. The total dose per shoulder was 27 J per treatment. Three sessions of LILT therapy per week were administered over a 3-week period. These parameters complied with the World Association for Laser Therapy recommendation for AC.[12]

Therapeutic exercises

After the laser applications, all participants performed 25 minutes of passive stretching of the shoulder joint, Codman exercises, and active-assisted range of motion exercises under the supervision of the same physiotherapist five times a week for 3 weeks (10 reps, 3 sets, 3 minutes rest between sets).[7]

Outcomes

All assessments were made by an investigator who was blinded to the patient group assignment. All assessments were done both before and 3 weeks after treatment.

Primary outcome

The Visual Analog Scale (VAS) was used to monitor and evaluate the intensity of pain. This is a patient-reported outcome tool that uses a 10-cm ruler, wherein patients can choose no pain at one end (Score 0) and the most intense pain at the other (Score 10).[13]

Secondary outcomes

The active range of shoulder motion (flexion, abduction, internal, and external rotation) was assessed using a universal goniometry in the supine position. The severity of pain and limitation experienced by individuals during certain activities were evaluated with the Shoulder Pain and Disability Index (SPADI). SPADI is a two-section patient-reported outcome evaluation tool that takes approximately 5–10 minutes to complete and comprises questions regarding pain and disability in the shoulder.[14] The first part consists of five questions that evaluate the worst pain level being experienced in the past 14 days, lying on the affected side, and the level of pain during reaching up, reaching behind the neck, and pushing activity. The second part evaluates the disability level by determining the level of limitation experienced by the individual during personal care, dressing, and carrying activities. The total score range in the scale ranges from 0 to 130. The answers given to the questions are calculated in percentile. Obtaining the high percentile indicates that the severity of the disability situation has increased. The validated and reliability assessed Turkish language version of SPADI was used in this study.[15]

Statistical analysis

Descriptive data are presented as mean ± standard deviation (SD). Chi-square test was performed to compare clinical and demographic characteristics. Shapiro–Wilk test was used for the conformity of continuous variables to normal distribution. All variables showed normal distribution. Paired sample *t*-test was used for in-group comparison of parametric-dependent data. Student *t* test was used for the comparison of parametric-independent data between groups. Statistical analysis was performed using SPSS (IBM 21.0. Armonk, NY:IBM Corp). *P* value < 0.05 was considered statistically significant.

RESULTS

A total of 40 patients with AC completed the present study: 20 patients in each group received the intended treatment

and were analyzed for the outcomes [Figure 1]. The baseline demographic and clinical characteristics of the patients are represented in Table 1, with no significant difference in any variable between both groups.

At the beginning of the study (baseline), there was no significant difference between the two groups in terms of VAS, SPADI, and goniometric scores ($P > 0.05$). After 3 weeks of treatment, both the LLLT and HILT groups showed significant improvement in the VAS ($P = 0.022$ and $P < 0.001$, respectively) and SPADI ($P = 0.038$ and $P < 0.001$, respectively) scores. In the inter-group comparison, improvements in VAS and SPADI scores were significantly greater in the HILT group than those in the LLLT group ($P < 0.001$) [Table 2]. There was no significant improvement in goniometric scores in both groups compared with baseline (flexion: $P = 0.382$, abduction: $P = 0.702$; internal rotation: $P = 0.665$; and external rotation: $P = 0.612$) [Table 3].

No injury or other musculoskeletal complications were recorded during the treatment and the 3-week follow-up period.

DISCUSSION

This randomized study is, to the best of our knowledge, the first study that compares LLLT with HILT for the management of AC. The VAS and SPADI scores in both groups significantly improved in the 3 weeks after treatment, but these improvements were significantly greater in the HILT group.

LLLT is a conservative treatment option in the management of shoulder musculoskeletal disorders such as shoulder impingement syndrome, rotator cuff tendinitis, and AC.[4,16,17] In a systematic review, evidence suggesting that LLLT reduced pain was high, while that for improving function was moderate; no evidence was found for improving range of motion. In the same review, exercises were highly suggested to reduce pain, improve function, and range of motion.[4] Similarly, another systematic review found that in patients with shoulder musculoskeletal disorders, there is moderate evidence suggesting that the addition of LLLT to exercise provides short-term benefits in pain management, but low evidence suggest there are

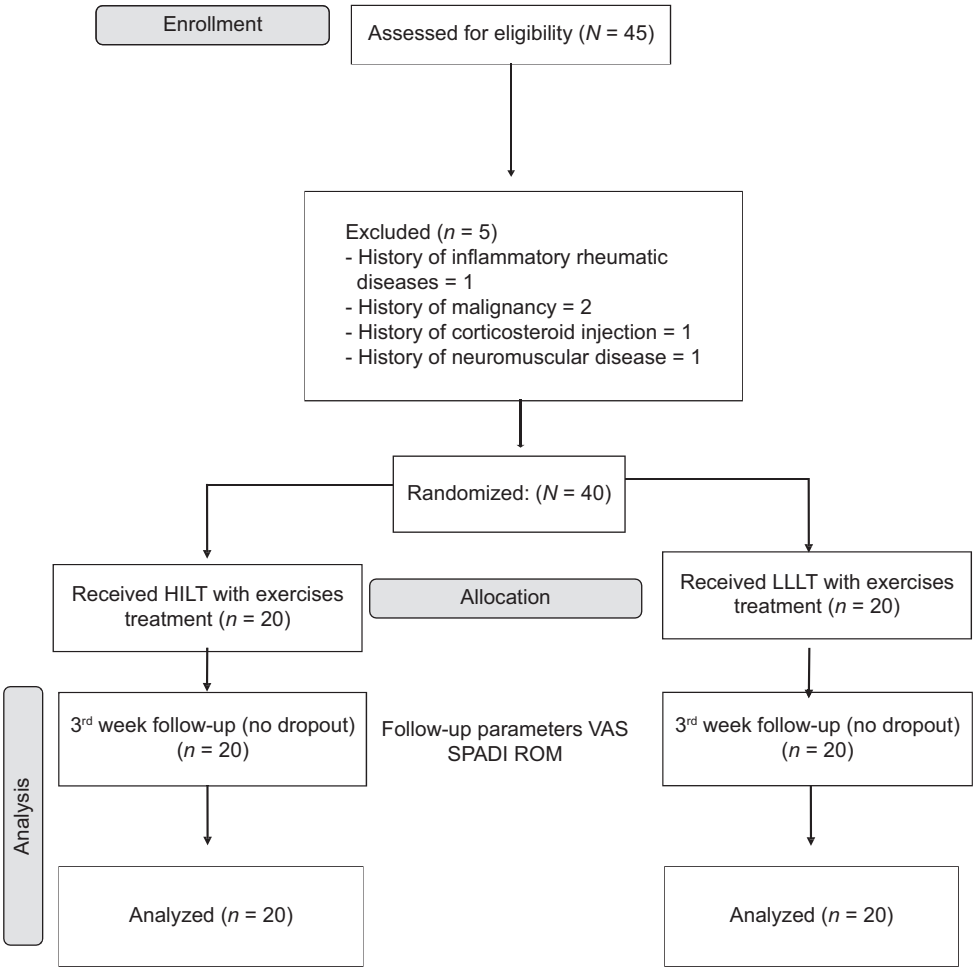

Figure 1: Flow diagram of the participants. HILT – High-intensity laser therapy; LLLT – Low-level laser therapy; VAS – Visual analog Scale; SPADI – Shoulder pain and disability index; ROM – Range of motion

no such added benefits in improving the range of motion and function.[18] Similarly, the current study also found that in the short term, LLLT + exercise resulted in significant improvements in function and pain reduction, but not in shoulder range of motion.

The clinical effectiveness of LLLT was demonstrated by Moshkovska and Mayberry.[19] Further, *in vitro* studies demonstrated that LLLT facilitates the stimulation of fibroblasts and collagen synthesis in connective tissue repair. In addition, there is evidence that LLLT modulates pain and reduces inflammation through the prevention of cyclooxygenase-2 and reduction of prostaglandin E2 receptor concentration. Animal studies have shown that low-level laser radiation (780 nm) in injured rat sciatic nerve stimulates peripheral nerve recovery by increasing axonal growth.[18,19]

HILT, namely, pulsed Nd: YAG laser therapy, has been used in a wide variety of disorders including, subacromial impingement syndrome,[20] knee osteoarthritis,[21] spinal disorders,[22] facial palsy,[23] and lateral epicondylitis.[24] Kim *et al*.[25] evaluated the efficacy of HILT in the treatment of AC and applied a total of 9 sessions of treatment for 3 weeks. When compared with placebo control after treatment, a significant improvement was detected in pain level, but not in range of motion and patient satisfaction. Importantly, that study was not able to provide evidence that the patients regularly did their exercises during the follow-ups. Nonetheless, the current study substantiates the findings of Kim *et al*., as HILT + exercise done under the supervision of a physiotherapist similarly found a significant reduction in pain but not in the range of motion. However, Atan *et al*.[9] applied 15 sessions of HILT therapy in the treatment of AC and demonstrated significant improvement in pain

Table 1: Comparison of demographic and clinical characteristics of the patients in both groups

Characteristic	HILT (*n*=20)	LLLT (*n*=20)	*P*
Age (years), mean±SD	54.5±8.9	55.6±7.9	0.547
Gender (female/male) (*n*)	16/4	15/5	0.810
Dominant side (right/left) (*n*)	20/0	20/0	
Symptomatic side (right/left) (*n*)	9/11	8/12	0.625
Body mass index (kg/m^2), mean±SD	28.22±2.30	29.45±2.20	0.718
Duration of symptoms (months), mean±SD	6.60±1.30	5.80±1.60	0.840

Chi-square test. HILT – High-intensity laser therapy; LLLT – Low-level laser therapy; SD – Standart deviation

Table 2: Assessment of Visual Analog Scale and Shoulder Pain And Disability Index before and after treatment

Assessment Tool	HILT (*n*=20)		LLLT (*n*=20)		*P* (inter group)
	Mean±SD	*P* (intra-group)	Mean±SD	*P* (intra-group)	
VAS					
Baseline	7.55±1.40	<0.001	7.42±1.52	0.022	0.648
After 3 weeks	2.20±1.62		4.73±1.20		0.038
SPADI pain					
Baseline	85.44±10.18	<0.001	84.28±10.09	0.028	0.502
After 3 weeks	42.23±10.05		50.62±9.98		<0.001
SPADI disability					
Baseline	82.62±14.50	<0.001	83.17±14.64	0.033	0.552
After 3 weeks	51.40±14.80		58.41±14.23		<0.001
SPADI total					
Baseline	80.11±14.95	<0.001	81.01±14.18	0.038	0.546
After 3 weeks	53.32±14.02		61.54±14.55		<0.001

Samples *t*-test; paired samples *t*-test. HILT – High-intensity laser therapy; LLLT – Low-level laser therapy; VAS – Visual analog Scale; SPADI – Shoulder pain and disability index; SD – Standard deviation

Table 3: Assessment of range of motion of shoulder joint values before and after treatment

Variable	HILT (*n*=20)		LLLT (*n*=20)		*P* (inter group)
	Mean±SD	*P* (intra-group)	Mean±SD	*P* (intra-group)	
Active flexion					
Baseline	95.55±14.06	0.422	97.42±13.52	0.432	0.657
After 3 weeks	102.20±13.78		104.62±14.30		0.382
Active abduction					
Baseline	65.34±11.86	0.613	67.12±12.08	0.648	0.642
After 3 weeks	69.24±12.05		70.51±11.98		0.702
Active internal rotation					
Baseline	32.32±8.50	0.636	35.13±7.94	0.618	0.553
After 3 weeks	35.42±8.24		38.23±8.12		0.665
Active external rotation					
Baseline	45.12±14.84	0.576	48.10±14.18	0.588	0.576
After 3 weeks	49.22±13.92		52.34±14.54		0.612

Samples *t*-test; paired samples *t*-test. HILT – High-intensity laser therapy; LLLT – Low-level laser therapy; SD – Standard deviation

and quality of life compared with sham laser + exercise and exercise alone groups. They also showed improvement in joint range of motion in all groups. This contrast with our finding of no difference in range of motion may be due to the number of sessions being applied differing, and future studies could be conducted to determine the optimal number of sessions to achieve effective treatment outcomes.

Stretching exercises along with physical therapy modalities can be strongly recommended to improve the pain levels, range of motion, and functional status of patients with AC.[26] HILT has been known to reduce inflammation and painful symptoms by increasing cell metabolism, vascular permeability, and blood flow.[7,8,27]

In patients with AC, pain restricts patients compliance with exercise, especially in the early phases. In such cases, laser applications are more effective in providing the analgesic effect.[28,29] However, adequate time is required to improve muscle function and the range of motion, and thus longer duration follow-up studies are required to substantiate the long-term effects of laser application.

In a study evaluating the effect of HILT on clinical outcomes and ultrasonographic measurements in patients with hemiplegic shoulder pain accompanied by partial rotator cuff tear, co-administration of HILT with therapeutic exercise was shown to be more beneficial than therapeutic exercise alone in improving pain, disability, function, and quality of life. In addition, it has also been shown to cause a significant reduction in the size of the tear in ultrasonographic measurements.[30] Owing to its specific properties such as analgesic effects on nerve endings and photothermic and photochemical effects that increase cell metabolism, vascular permeability and blood flow, HILT is an effective method for controlling patient pain and treating deep tissues and structures in the short term.[21]

The current study found that HILT treatment was more effective than LLLT in reducing pain and improving the functional parameters in patients with AC. Studies that have compared the efficacy of LLLT and HILT for different conditions found similar results. Alayat *et al*.[23] showed that HILT combined with exercise was more effective than LLLT in aiding recovery in patients with Bell's palsy. Similarly, another study showed that HILT was more effective than LLLT in improving hand grip strength, functional parameters, and quality of life in patients with lateral epicondylitis.[24] Ordahan *et al*.[31] found that while HILT and LLLT both reduced pain and improved functional status and quality of life in patients with plantar fasciitis, HILT was more effective than LLLT. Conversely, in one study in patients with plantar fasciitis, no significant difference was found between the HILT and LLLT groups in VAS, pressure algometry, and ultrasonographic measurements; however, HILT was found to score significantly higher in participant's opinion of treatment efficacy.[32] The inconsistency in findings in patients with plantar fasciitis may be due to differences in laser application protocols. Currently, there is no clear information or guideline about the application indication, period, frequency, wavelength, and mode (pulse or continuous) of laser in the management of AC.

Collectively, from our findings and that of other studies, the application of laser in combination with exercise would likely be a viable treatment strategy for patients with AC, as laser use has minimal associated pain and side effects. However, further similar studies may be conducted with the added inclusion of an exercise alone group and with a longer follow-up duration to estimate the added benefits laser use provide in both the short and long term.

Limitations

The most important limitation of the study is the short follow-up period. Another limitation is the absence of a placebo control group. In addition, although the study design is robust, the optimal frequency, dose, and wavelength of LLLT and HILT are not yet known, which may limit the generalizability of the findings, and thus further studies may be needed to determine optimal treatment regimen.

CONCLUSION

This study revealed that a 3-week application of HILT is more effective than LLLT in reducing pain and improving functional parameters in patients with AC.

Trial registration

The study was registered in ClinicalTrials.gov (Identifier: NCT05469672).

Ethical considerations

The study was approved by the Research Ethics Committee (Ref. No: 2042; date: September 13, 2019), Faculty of Medicine, The Necmettin Erbakan University, Konya, Turkey. All study participants provided written consent before inclusion in the study. The study adhered to the principles of the Declaration of Helsinki, 2013.

Peer review

This article was peer-reviewed by two independent and anonymous reviewers.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author contributions

Conceptualization: OB, YF; Methodology: OB, YF, MC; Writing–original draft preparation: OB, YF, MC; Writing – review and editing: OB, YF, MC.

All authors have read and agreed to the published version of the manuscript.

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Conflicts of interest

There are no conflicts of interest.

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