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RESEARCH

Effect of high-intensity laser therapy on supraspinatus tendon elasticity in subacromial impingement syndrome: A double-blind randomized controlled study

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Abstract

This study primary aimed to evaluate the effect of high-intensity laser therapy (HILT) on the elasticity of the supraspinatus tendon in participants with subacromial impingement syndrome (SIS) and secondary aimed to evaluate the effect of HILT on pain and function. This randomized controlled double-blind study included 66 participants diagnosed with SIS and were randomly assigned into HILT group (HILT and physical therapy) and control group (sham HILT and physical therapy) and received 10 sessions (five days a week during two weeks). Supraspinatus tendon elasticity was measured by shear wave elastography (SWE). Pain and function were assessed by visual analog scale (VAS) and shoulder pain and disability index (SPADI), respectively. Measurements were made at baseline and after treatment. The minimal clinically important difference (MCID) was accepted as 1.37 for VAS and 13.2 for SPADI. There was no difference in SWE measurements before and after treatment in both groups ($p>0.05$). VAS and SPADI showed clinically and statistically significant improvement in the HILT and control groups ($p<0.001$). The r value for VAS and SPADI in the HILT group was calculated as 0.97; and 0.97 for VAS and 0.96 for SPADI in the control group. A statistically significant difference was found in VAS and SPADI in the HILT group compared to the control group ($p=0.010$, $p<0.001$, respectively). However, the differences were not clinically significant (mean differences 0.5 and 6.41, respectively). This study concluded that HILT applied together with physical therapy had no effect on tendon elasticity in the short term. Besides, HILT combined with physical therapy is statistically more effective in reducing pain and improving function than physical therapy alone.

Keywords Elasticity imaging techniques · Laser therapy · Rotator cuff · Shoulder pain · Stiffness

Introduction

Subacromial impingement syndrome (SIS) is one of the most common causes of shoulder pain and is associated with pain and disability [1, 2]. SIS develops due to compression of one or all of the rotator cuff tendons, the long tendon of the biceps brachii, or the subacromial bursa in the subacromial space due to intrinsic or extrinsic causes. Extrinsic causes lead to compression of the tendons in the subacromial space due to anatomical or biomechanical abnormalities (such as subacromial spur, acromion shape, acromioclavicular spur). Degeneration in the tendon that exceeds the intrinsic healing and adaptive responses constitutes the intrinsic cause [3]. Varying degrees of inflammation and tendon degeneration are observed in SIS [4]. Histomorphological changes include decreased tenocyte count, increased apoptosis, increased matrix metalloproteinases (MMP), decreased

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collagen density, irregular orientation of collagen, and disruption of the extracellular matrix [5–7].

The main goals of treatment for SIS are to correct the mechanical disorder causing subacromial impingement and to reduce pain [8]. Treatments such as strengthening exercises for periscapular and rhomboid muscles, corticosteroid injections, laser therapy, mobilization, extracorporeal shockwave therapy are some of the conventional rehabilitation treatments applied in the treatment of SIS [9–13].

Laser therapy is a noninvasive and painless treatment method used to reduce pain in musculoskeletal disorders which has analgesic, anti-inflammatory and bio stimulation effects with its local and systemic effects. These positive results may be attributed to the effects of laser in inhibiting the activity of MMP [14] reducing the concentration of the inflammatory marker PGE2 [15] increasing collagen synthesis [16, 17] and angiogenesis [18]. Additionally, it increases tendon healing by reducing oxidative stress and fibrosis [19]. Laser treatment is applied in two ways, low-intensity laser and high-intensity laser therapy (HILT), depending on the wavelength and maximum output power. HILT has an emission wavelength of 1.064 nm and a power of 3.000 Watts. HILT reaches deeper tissues than low-intensity laser [20]. A recent meta-analysis has shown that HILT is superior to conventional treatments in reducing pain and enhancing function in the short and long term in SIS [21].

Shear wave elastography (SWE) is an ultrasonography technique that uses acoustic radiation to create shear waves in tissue and analyze the propagation speed of these waves to measure tissue elasticity. The elasticity/stiffness properties of tendons are given quantitatively in units of shear wave velocity (SWV) (m/s) or Young's modulus (kPa) [22]. Tendons have a characteristic coefficient of elasticity related to their mechanical properties. Degenerative changes, increased collagen type 3 fibers and fibrocartilaginous changes due to overload lead to decreased stiffness of tendons and different elasticity patterns [23]. To date, research has shown that tendons that develop tendinopathy are less stiff/elastic than normal tendons [24, 25]. Hackett et al. reported that the mean SWV of the normal supraspinatus tendon was 9.96 ± 0.02 m/s (297 kPa); the mean SWV of the tendinopathic supraspinatus tendon was 8.3 ± 0.2 (207 kPa) [24].

HILT is known to heal pain and function in SIS, but its effect on the mechanical properties of the supraspinatus tendon is unknown. The mechanical properties of the tendon are determined by collagen, proteoglycans, and glycosaminoglycans [3]. We hypothesized that HILT would increase tendon elasticity by increasing collagen synthesis. Therefore, in this study, we aimed to research the effect of HILT on the elasticity of the supraspinatus tendon in participants with SIS using SWE.

Materials and methods

Study design

This study was planned as a randomized, double-blind, parallel group and 1/1 allocation ratio. The study protocol was confirmed by the Hasan Kalyoncu University Ethics Committee with decision number 2024/85 and registered at ClinicalTrials.gov (Clinical Trial Number: NCT06514105, Registration Date: July 2024). The Declaration of Helsinki was followed throughout the study. The data obtained were recorded in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomised trials [26].

Participants

Participants who applied to the physical medicine and rehabilitation clinic of a tertiary hospital with shoulder pain and were diagnosed with SIS by the PRM physician were evaluated for their eligibility to participate in the study. SIS was diagnosed based on the participants' clinical findings and physical examination. Provocative tests for SIS (Hawkin's test, Neer impingement sign, painful arc test) were applied during physical examination to participants with anterior or lateral shoulder pain and increased shoulder pain during overhead activities. When the tests were positive, 10 mL of 1% lidocaine was injected into the subacromial space to confirm the diagnosis. The disappearance of pain triggered by provocative tests after the injection confirmed the diagnosis. Additionally, participants were evaluated with anteroposterior shoulder radiographs. The eligibility criteria were as follows: diagnosis of SIS, volunteering to be included in the study, being between 30–60 years of age, shoulder pain lasting at least 6 weeks. The exclusion criteria were as follows: calcific tendinitis, adhesive capsulitis, trauma or shoulder surgery history, steroid injections or physiotherapy (including extracorporeal shockwave therapy) to the shoulder within the last 6 weeks, presence of cervical radiculopathy, inflammatory disease and pregnancy. All participants were informed about the study in advance and written consent was obtained from each participant.

Interventions

Physical therapy (PT) and HILT were applied to the HILT group ($n = 33$), and PT and sham HILT were applied to the control group ($n = 33$). The treatments were applied by the same physiotherapist.

PT All participants included in the study received a PT program 5 days a week for 2 weeks. The PT program includes

hot pack (15 min to the shoulder area), transcutaneous electrical stimulation (TENS) (20 min with the BTL 4000 combined device), ultrasound (5 min, 1.5W/cm2 dose, 1-MHZ frequency, 5-cm ultrasound head to the subacromial area) and home exercise program. The home exercise program consists of active range of motion exercises, stretching and strengthening exercises (3 sets, 10 repetitions, 5 days a week for two weeks) including rotator cuff, rhomboid muscles, levator scapula, serratus anterior and pectoral muscles [27].

HILT HILT was performed with the BTL-6000 (BTL Company, UK) device with the patient in a sitting position. HILT was applied 5 days a week for 2 weeks. Treatment sessions were applied in two modes, analgesic (pulsed mode) and bio stimulation mode (continuous wave mode), in accordance with the literature [28]. Analgesic mode (power 10 W, dosage 10 J/cm^2, area 25cm^2, total maximal energy 250 J, frequency 25 Hz, duration 100 s) was applied to the subacromial region by making circular movements in the first 5 sessions. Bio stimulation mode (power 4 W, dosage 100 J/cm^2, area 25cm^2, total maximal energy 2500 J, duration 10 min 30 s) was applied to the subacromial space by making linear movements in the last 5 sessions. Safety measures have been taken to prevent the negative effects of the laser. During the treatment, both the participant and the physiotherapist wore special eye protection goggles to prevent damage to the eye retina.

Sham HILT The device power is set to 0W. With the guide light on, it was applied to the subacromial region with circular movements for the same duration. Participant and physiotherapist wore goggles as a safety precaution.

Outcome measures

Gender, age, body mass index (BMI), symptom duration, and affected extremities of all participants were recorded before treatment. Participants were evaluated before and after treatment (Week 2). The primary outcome of the study was measurement of elasticity of the supraspinatus tendon. This measurement was made by a radiologist blinded to the group allocation who has thirteen years of experience in musculoskeletal radiology. Secondary outcomes of the study were assessment of pain and shoulder function. This measurement was made by a PMR physician blinded to the group allocation who has ten years of experience.

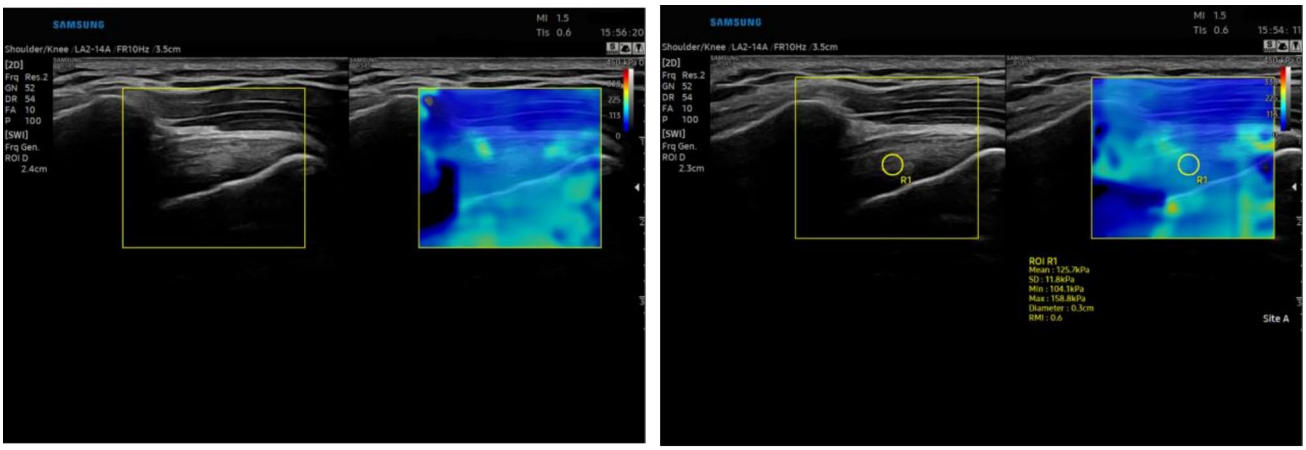
Elasticity measurement Elasticity measurement of the supraspinatus tendon was performed by SWE using the Samsung RS85 Prestige device and the LA2-14A linear probe. A good to perfect intra- and inter-observer agreement (ICC = 0.7–0.970 and ICC = 0.45–0.948, respectively) [22, 29] was reported for assessing the supraspinatus tendon with SWE. Measurements were made with the participant in a sitting position, shoulders in neutral, elbow in 90-degree flexion, and the supraspinatus muscle at rest. During B-mode scanning, the supraspinatus tendon was imaged longitudinally and parallel to the probe in the oblique coronal plane. During SWE mode analysis, color maps were created to visualize shear wave velocities via a rectangular measurement box superimposed on the grayscale images. In this color maps, four regions of interest with a diameter of 3 mm were placed on the supraspinatus tendon (Fig. 1). SWV (maximum 10 m/s) and Young's modulus (maximum 300 kPa) were measured quantitatively in these regions. The measurement was repeated four times and the mean of these measurements was recorded.

Pain The pain level of the participants was evaluated with a visual analog scale (VAS). The VAS consists of a 10 cm long horizontal line, with the left end representing no pain and the right end representing unbearable pain [30]. Participants were asked to mark the pain they felt on the VAS, and this value was measured and recorded with the help of a ruler. The minimal clinically important difference (MCID) for VAS in rotator cuff pathologies has been reported as 1.37 [31].

Functional level The functional level of the participants was evaluated with the shoulder pain and disability index (SPADI). The SPADI is a questionnaire with proven validity and reliability that assesses pain and disability in a variety of shoulder disorders [32]. It consists of a five-item pain scale and an eight-item disability scale. Each item is scored between 0 and 10. Total pain score is computed with the formula _/50 × 100. Total disability score is computed with the formula _/80 × 100. The total SPADI score is computed by averaging the pain and disability scales. 0 is the lowest score, 100 is the highest score. Higher scores indicate more disabilities. Turkish validity and reliability were made by Bumin et al. [33]. MCID for SPADI in shoulder pathologies has been reported as 13.2 [34].

Sample size

There is no study investigating the efficacy of HILT on supraspinatus tendon elasticity. Therefore, the sample size of this study was decided according to secondary outcomes. Previous study has shown that HILT has large effect sizes on pain (VAS) and function (QuickDASH scale) [12]. Sample size analysis was performed using the G*Power® 3.1.9.7 software, applying the t test: "Means: Difference between two independent means (two groups)". It was calculated that 60 patients should be included with inputs of effect size



A B

Fig. 1 Elasticity measurement of the supraspinatus tendon. **A** On the left, a longitudinal B-mode ultrasound image of the supraspinatus tendon is presented, with the corresponding shear wave elastogram color map for the same region displayed on the right. **B** Automatic generation of shear wave velocity and local stiffness values is achieved through the placement of a 3 mm diameter circular region of interest (ROI) on the supraspinatus tendon, as visualized on the shear wave elastogram color map

0.80, alpha 0.05, power 0.85, allocation ratio 1/1. A total of 66 participants were included in this study, considering that there may be a 10% drop-out.

Randomization and blinding

Participants diagnosed with SIS by a physical and rehabilitation medicine (PRM) physician were included in the study. The first author, who was not involved in data collection, created a randomization file using a computer-based allocation program (http://www.randomizer.org). Participan ts were assigned to the HILT group and the control group according to a 1:1 distribution randomization algorithm. Sealed and sequentially numbered opaque envelopes were used for concealed allocation. Participants who agreed to participate in the study were asked to randomly choose one of these envelopes. The first author, who has at least ten years of experience in orthopedic rehabilitation, opened the envelope and administered the treatment according to the group allocation. Participants were blinded to group assignment; they were aware that they would receive a treatment but did not know the content of the intervention. Data collection was performed by a radiologist and a PRM physician blinded to group allocation before and after treatment.

Statistical analysis

In the statistical analysis performed with SPSS 22, the conformity of the data to normal distribution was determined according to the Skewness and Kurtosis values. It was determined that the numerical variables showed normal distribution. These values (age, symptom duration, BMI, SWE scores, SPADI and VAS) were given with mean and standard deviation values. Categorical variables such as gender and dominant extremity were given as numbers and percentages. Intragroup comparisons were made using the paired samples t test. Differences between the HILT group and the control group were determined using Student's t test for numerical variables and chi-square test for categorical variables. The r value was calculated for the effect size (0.1 small, 0.3 medium, 0.5 large effect size) [35]. MCID values for VAS and SPADI were compared with values reported in the literature [31, 34]. A $p<0.05$ was accepted adequate for statistical significance.

Results

Between July 2024 and March 2025, 81 participants were assessed for eligibility. 66 participants meeting the eligibility criteria were included in the study. The CONSORT flow chart is given in Fig. 2. The study was terminated when the calculated sample size was reached.

Gender, age, BMI, dominant extremities, symptom duration and baseline measurements of the groups are given in Table 1. There was no statistical difference between the groups ($p>0.05$).

Differences between groups before and after treatment are given in Table 2. There was no difference in SWE measurements (SWV and Young's modulus scores) before and after treatment in both groups ($p>0.05$). A statistically significant difference was found in SPADI and VAS measurements before and after treatment in both HILT and control groups ($p<0.001$). The mean differences were higher than the MCID values (13.2 and 1.37, respectively) reported in the literature in both groups. The effect size for VAS and

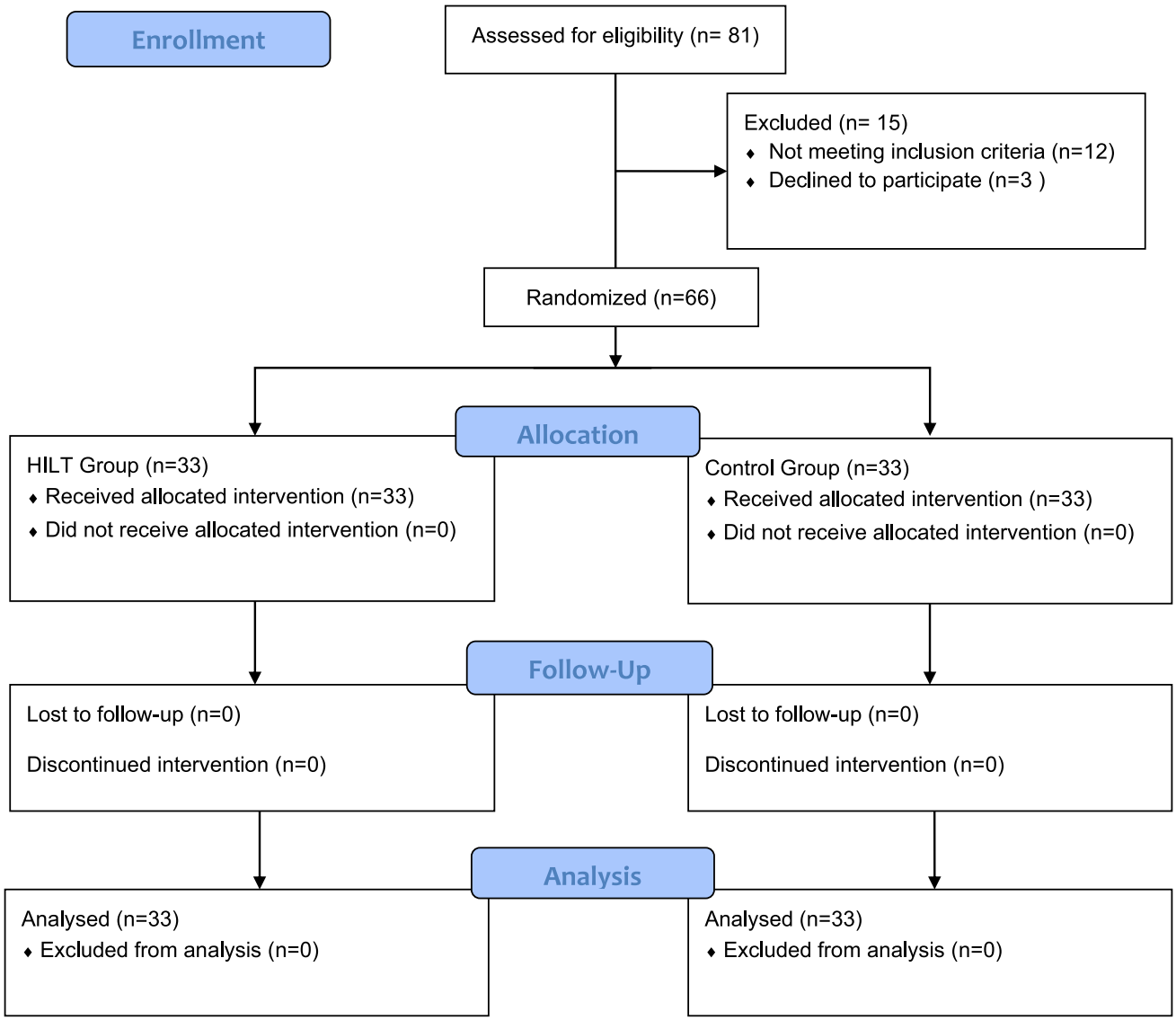


Fig. 2 CONSORT flow chart of participants

SPADI in the HILT group was calculated as 0.97; and 0.97 for VAS and 0.96 for SPADI in the control group.

Comparisons of post-treatment measurements between the HILT and control groups are given in Table 3. No difference was found between the groups in SWE measurements ($p>0.05$). There was a statistical difference between the HILT and control groups in SPADI measures ($p<0.001$). The effect size was calculated as r=0.46. The SPADI measures in the HILT group were on mean 6.41 points lower than the control group. This difference is less than the MCID value. There was a statistical difference between the HILT and control groups in VAS measures ($p=0.010$). The effect size was calculated as r=0.31 The VAS measures in the HILT group were on mean 0.9 points lower than the control group. This difference is smaller than the MCID value.

No participant complained or reported adverse effects after treatment.

Discussion

To our knowledge, our study is the first study aimed to research the effectiveness of HILT combined with PT on tendon mechanical properties, pain and function parameters in SIS by comparing it with a PT alone. Our findings showed that there was no change in tendon elasticity detectable by SWE in the short term in both groups. Both groups showed statistically (with large effect sizes) and clinically significant improvements in reducing pain and improving function. Besides, HILT combined with PT was found to be

Table 1 Baseline characteristics of groups

	HILT group	Control group	*p*-value
	Mean ± Sd *n* (%)	Mean ± Sd *n* (%)	
Age, *year*	44.6 ± 11.5	46 ± 9.5	0.595
BMI, *kg/m²*	25 ± 2.1	25.7 ± 2.8	0.276
Gender			
Female	17 (51.5)	14 (42.4)	0.459
Male	16 (48.4)	19 (57.5)	
Symptom duration, *w*	16.4 ± 0.9	15.2 ± 0.9	0.359
Affected extremity			
Dominant	20 (60.6)	19 (57.5)	0.802
Non dominant	13 (39.3)	14 (42.4)	
Baseline measures			
SWV, *m/s*	7.30 ± 0.62	7.30 ± 0.74	0.977
Young's modulus, *kPa*	164. 98 ± 27.14	164.82 ± 29.5	0.982
SPADI	58.32 ± 8.57	56.81 ± 10.84	0.531
VAS	7 ± 0.79	6.91 ± 0.87	0.660

SWV Shear wave velocity, *VAS* Visual analog scale, *SPADI* Shoulder pain and disability index, *HILT* High-intensity laser therapy, *BMI* Body mass index, *p-value:* Student's t test and chi-square test

statistically more effective in improving pain and function than PT alone.

HILT provides tendon healing with its physiological effects such as increasing collagen synthesis and reducing fibrosis. Knowing the changes in mechanical properties of tendons after HILT may be important to determine optimal treatment times and dosages and to elucidate the mechanisms associated with clinical outcomes. Corrigan et al. investigated the effects of a single session of low-intensity laser therapy on the mechanical properties of the Achilles tendon in participants with Achilles tendinopathy. Tendon properties were evaluated with SWE before and 4 h after treatment. No difference was detected in the mechanical properties of the Achilles tendon in the pre- and post-treatment measurements [36]. Marotta et al. investigated the effect of HILT on common extensor tendon elasticity in lateral epicondylitis. Before treatment, SWV was 1.69 ± 0.35 m/s, and after 10 sessions of HILT, SWV was 2.56 ± 0.36 m/s ($p < 0.001$) [37]. In our study, the measurements obtained in both groups

Table 3 Comparison of post-treatment measurements of groups

	Mean difference	95% Cl		*t*	*p*
		Lower	Upper		
SWV, m/s	0.08	−0.21	0.37	0.548	0.586
Young's modulus, *kPa*	3.13	−9.08	15.3	0.513	0.610
SPADİ	−6.41	−9.49	−3.33	−4.157	**< 0.001**
VAS	−0.545	−0.958	−0.133	−2.641	**0.010**

SWV Shear wave velocity, *SPADI* Shoulder pain and disability index, *VAS* Visual analog scale, *%95 Cl* Confidence interval, *p* Student's t test

before treatment were lower than the elasticity values of the healthy supraspinatus tendon reported in the literature [21]. No difference was found in SWV and Young's modulus values in both groups after treatment. Contrary to the study by Marotta et al., our findings showed that the HILT applied together with PT had no effect on the SWV. This difference may be related to the degree of tendinopathy and duration of symptoms. Marotta et al. included patients with elbow pain lasting at least 2 weeks in their study, but there is no information on the mean duration of symptoms. In our study, the mean symptom duration was 16.4 weeks in the HILT group and 15.2 weeks in the control group. We suggest developing treatment protocols longer than two weeks in order to see changes in tendon mechanical properties in chronic tendinitis.

The effects of various physical therapy modalities on SIS have been investigated. Santamato et al. compared HILT (10 sessions) and ultrasound (10 sessions) treatment in SIS. Pain was assessed with VAS and function was assessed with the Constant Murley Scale. At the end of two weeks, there was a decrease in pain of 3.86 points in the HILT group and 2.17 points in the ultrasound group, and an increase in function of 12.69 points in the HILT group and 9.03 points in the ultrasound group. They reported that HILT was superior to ultrasound in improving pain and function [38]. Aceituno-Gómez et al. compared an intervention group (15 sessions, HILT and exercise) and a placebo group (15 sessions, sham HILT and exercise) in SIS. After treatment, VAS decreased

Table 2 Comparison of HILT and control groups before and after treatment

		Before treatment	After treatment	Mean D	%95 Cl	r	*p*
					Lower- Upper		
SWV, m/s	**HILT**	7.30 ± 0.62	7.35 ± 0.52	−0.04 ± 0.19	−0.11 – 0.02	-	0.204
	Control	7.30 ± 0.74	7.27 ± 0.66	0.03 ± 0.21	−0.04 – 0.10	-	0.411
Young's modulus, *kPa*	**HILT**	164.98 ± 27.14	166.49 ± 23.58	−1.5 ± 6.25	−3.72 – 0.7	-	0.175
	Control	164.82 ± 29.5	163.36 ± 26.05	1.46 ± 0.6.56	−0.86 – 3.79	-	0.209
SPADI	**HILT**	57.79 ± 8.45	25.07 ± 2.06	33.25 ± 8.10	30.38–6.12	0.97	**< 0.001**
	Control	56.81 ± 10.84	31.48 ± 8.61	25.32 ± 6.96	22.85–27.79	0.96	**< 0.001**
VAS	**HILT**	7 ± 0.79	2.76 ± 0.75	4.24 ± 0.96	3.91–4.57	0.97	**< 0.001**
	Control	6.91 ± 0.87	3.30 ± 0.91	3.6 ± 0.82	3.31–3.89	0.97	**< 0.001**

SWV Shear wave velocity, *SPADI* Shoulder pain and disability index, *VAS* Visual analog scale, *HILT* High-intensity laser therapy, *Mean D* Mean difference, *%95 Cl* Confidence interval, *p-value:* paired samples *t* test

by 1.8 and 2.1 points, and SPADI increased by 21.6 and 28.8 points in the groups, respectively. It was reported that HILT combined with exercise was no more effective than exercise alone [12]. In our study, HILT and PT were applied to the HILT group, and sham HILT and PT were applied to the control group. The PT consists of ultrasound, exercise and TENS, which have been shown to be effective in SIS in previous studies [12, 38, 39]. After treatment, large effect sizes were found in pain and function parameters in both groups, and the mean differences were higher than the MCID values. Although HILT combined with PT was statistically more effective in improving pain and function than PT alone, it did not show a clinically significant difference. This may be due to the sample size not being high enough to reveal a clinically significant difference. Finally, we suggest that HILT be applied as an effective and safe supportive treatment of PT in SIS.

The main strengths of our study are the randomized double-blind design and the investigation of both clinically meaningful improvement and statistically significant differences. However, the main limitation of the study is the lack of long follow-up period. Second, measurements were made in a resting position, but myoelectric activity was not recorded to ensure that the muscles were relaxed. Third, patients with partial or full-thickness tears of the supraspinatus muscle during B-mode scanning were excluded from the study. Ultrasonography is less sensitive than MRI in detecting partial tears. Therefore, we may have missed small partial-thickness tears. Finally, the participants'occupations and labor intensity were not assessed.

Conclusion

This study concluded that HILT applied together with PT had no effect on tendon elasticity in the short term. Besides, HILT combined with PT was found to be statistically more effective in reducing pain and enhancing function than PT alone. Future studies with larger samples and longer follow-up periods are expected to better understand the clinical significance of this difference and to determine the effect of HILT on tendon mechanical properties.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10103-025-04582-w.

Author contributions AA: design of research, drafted, edited and revised manuscript, MÖ: data collection; EA: data collection, SU: conception and design of research; HTB: drafted. All authors approved final version of manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Ethics and consent to participate The study protocol was confirmed by the Hasan Kalyoncu University Ethics Committee with decision number 2024/85. Written informed consent was obtained from the all participants.

Registration details The study was registered at https://www.clinicaltrials.gov/. Clinical trial number: NCT06514105. Registration Date: July 2024.

Competing interests The authors declare no competing interests.

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