Research Report

Short-term Effects of High-Intensity Laser Therapy Versus Ultrasound Therapy in the Treatment of People With Subacromial Impingement **Syndrome: A Randomized Clinical Trial**

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Background. Subacromial impingement syndrome (SAIS) is a painful condition resulting from the entrapment of anatomical structures between the anteroinferior corner of the acromion and the greater tuberosity of the humerus.

Objective. The aim of this study was to evaluate the short-term effectiveness of high-intensity laser therapy (HILT) versus ultrasound (US) therapy in the treatment of SAIS.

Design. The study was designed as a randomized clinical trial.

Setting. The study was conducted in a university hospital.

Patients. Seventy patients with SAIS were randomly assigned to a HILT group or a US therapy group.

Intervention. Study participants received 10 treatment sessions of HILT or US therapy over a period of 2 consecutive weeks.

Measurements. Outcome measures were the Constant-Murley Scale (CMS), a visual analog scale (VAS), and the Simple Shoulder Test (SST).

Results. For the 70 study participants (42 women and 28 men; mean [SD] age=54.1 years [9.0]; mean [SD] VAS score at baseline=6.4 [1.7]), there were no between-group differences at baseline in VAS, CMS, and SST scores. At the end of the 2-week intervention, participants in the HILT group showed a significantly greater decrease in pain than participants in the US therapy group. Statistically significant differences in change in pain, articular movement, functionality, and muscle strength (force-generating capacity) (VAS, CMS, and SST scores) were observed after 10 treatment sessions from the baseline for participants in the HILT group compared with participants in the US therapy group. In particular, only the difference in change of VAS score between groups (1.65 points) surpassed the accepted minimal clinically important difference for this tool.

Limitations. This study was limited by sample size, lack of a control or placebo group, and follow-up period.

Conclusions. Participants diagnosed with SAIS showed greater reduction in pain and improvement in articular movement functionality and muscle strength of the affected shoulder after 10 treatment sessions of HILT than did participants receiving US therapy over a period of 2 consecutive weeks.

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ubacromial impingement syndrome (SAIS) is the entrapment of the supraspinatus muscle tendon between the anteroinferior corner of the acromion and the greater tuberosity of the humerus.1 This entrapment is responsible for degenerative lesion's of the tendon. Several pathoetiological mechanisms have been proposed; these include continuous lesions caused during the movement of the arm by subacromial contact, the subcoracoid space, the coracoacromial ligament, and the coracoacromial articulation; alteration of acromial morphology²; alteration of arterial vascularization of the humeral head3-5; overuse syndrome; and alteration of the tensile properties of the supraspinatus tendon.6

Subacromial impingement syndrome is characterized by severe pain in the anterior-posterior and lateral shoulder, extending to the deltoid and biceps areas. The painful symptoms increase at night and during abduction, forced internal rotation, and resisted motions. Neer^{7,8} described 3 stages of impingement. Stage I impingement is characterized by edema and hemorrhage of the subacromial bursa and rotator cuff and typically is found in patients who are less than 25 years old. Stage II impingement represents irreversible changes, such as fibrosis and tendinopathy of the rotator cuff, and typically is found in patients who are 25

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to 40 years old. Stage III impingement is marked by more-chronic changes, such as partial or complete tears of the rotator cuff, and usually is seen in patients who are more than 40 years old.

Management of this pathology includes numerous interventions, depending on pain severity and anatomopathological classification. Analgesic and nonsteroidal antiinflammatory drugs,9 steroid injections,10 and physical therapy (ultrasound [US] therapy, laser therapy, manual therapy, extracorporeal shock wave therapy, interferential current therapy, and acupuncture)11-22 have been reported, often with mixed results. Systematic reviews of clinical trials have demonstrated little benefit from nonsteroidal anti-inflammatory drugs and steroid injections; some studies have suggested various physical agents to be effective in minimizing the symptoms by reducing inflammation.²³ Although pain can reduce their efficacy, rehabilitative exercise approaches for the treatment of SAIS include active and passive range of motion (ROM) exercises, stretching, Codman exercises, and isometric and isotonic exercises. 19,23,24 The effectiveness of conservative treatment is mixed, and surgical treatment may be indicated in cases resistant to conservative treatment.25

Several systematic reviews have suggested that physical therapy has not provided unequivocal results because of the notable variability of anatomopathological lesions. 11-22 In particular, limited evidence has suggested that exercise, joint mobilization, and laser therapy are effective in decreasing pain and improving function in patients with SAIS. 20,22 Some systematic reviews have reported the limited effectiveness of US therapy for this condition. 20,21 However, other studies have shown US therapy to be effective in improv-

ing the symptoms.^{26,27} According to the recommendations of the Philadelphia Panel, an expert panel on selected rehabilitation interventions for shoulder pain, US therapy is an acceptable physical therapy intervention for SAIS.¹⁶

Laser therapy is based on the belief that laser radiation (and possibly monochromatic light in general) is able to alter cellular and tissue functions in a manner that is dependent on the characteristics of the light itself (eg, wavelength, coherence).28 By definition, low-intensity laser therapy (LILT) (often also known as "low-energy" or "low-power" laser therapy) takes place at low radiation intensities. Therefore, it is assumed that any biologic effects are secondary to the direct effects of photonic radiation and are not the result of thermal processes.²⁹ More recently, high-intensity laser therapy (HILT), which involves higher-intensity laser radiation and which causes minor and slow light absorption by chromophores, has been used. This absorption is obtained not with concentrated light but with diffuse light in all directions (scattering phenomenon), increasing the mitochondrial oxidative reaction and adenosine triphosphate, RNA, or DNA production (photochemistry effects) and resulting in the phenomenon of tissue stimulation (photobiology effects).30

Some systematic reviews and randomized clinical trials have suggested that LILT could be an effective physical therapy intervention for decreasing pain and functional loss or disability for patients with SAIS^{20,31,32} or could have analgesic and tissue repair actions.³³ Nonetheless, the effectiveness of laser therapy is still in question because LILT has not provided convincing results in patients with shoulder tendinopathies.^{34,35}

Few studies have been conducted to compare the effectiveness of different physical therapies³⁶ because of the difficulty in selecting homogeneous groups of patients to reduce the variability of the results. To our knowledge, no studies to date have been conducted on the possible effects of HILT on SAIS. The aim of the present study was to evaluate the short-term effectiveness of 2 different physical therapy modalities in the treatment of SAIS: HILT and US therapy.

Method **Setting and Participants**

Consecutive outpatients attending the Department of Physical Medicine and Rehabilitation, University of Foggia, from September 2006 to July 2007 were invited to participate in the study. Patients had experienced shoulder pain for at least 4 weeks before the study. Diagnostic criteria for SAIS were the presence of shoulder pain, pain on abduction of the shoulder with a painful arch, a positive impingement sign (Hawkins sign),37 and a positive impingement test (relief of pain within 15 minutes after the injection of a local anesthetic [bupivacaine, 5 mL]) into the subacromial space). All patients also were evaluated by ultrasonography or magnetic resonance imaging of the shoulder to confirm the diagnosis of stage I or II.7 We used the diagnostic criteria for ultrasonography described by Naredo and colleagues.38 This technique included a dynamic examination of the supraspinatus tendon obtained by moving the patient's arm from a neutral position to 90 degrees of abduction to detect encroachment of the acromion into the rotator cuff.

Patients were excluded from the study if they met any of the following criteria: anesthetic or corticosteroid injections within 4 weeks of study enrollment, surgery or previous fractures of the humeral head of the affected shoulder, impaired rotation in the glenohumeral joint (as measured with goniometry), a history of acute trauma, known osteoarthritis in the acromioclavicular or glenohumeral joint, calcifications exceeding 2 cm in the rotator cuff tendons, signs of a rupture of the cuff, cervical myofascial pain syndrome, radicular pain, inflammatory rheumatic disease, systemic lupus erythematosus, diabetes mellitus type I or II, thyroid dysfunctions, pacemaker, neurological pathologies, or anxiety-depression syndromes.

Patients received no other physical therapy intervention for shoulder pain during the study or in the 4 to 5 weeks before the study. After a complete description of the study was provided, written informed consent was obtained from all subjects or their relatives. The participants were instructed to avoid analgesic or antiinflammatory drugs for the duration of the treatment and to abstain from the execution of painful activities of daily living involving the affected shoulder. The participants kept a daily log of analgesic or antiinflammatory drug intake during the study period.

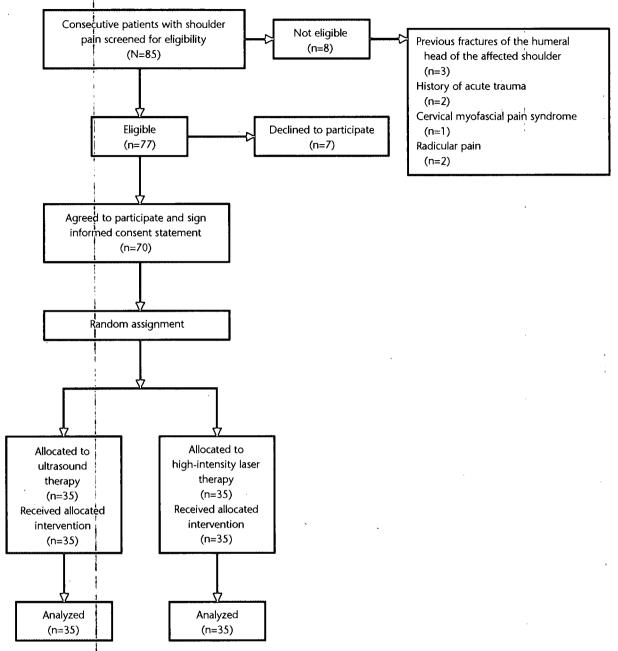
A total of 85 consecutive patients (50 women and 35 men) were screened for study eligibility. At the end of the evaluation, 70 patients who were affected by SAIS (Neer stage I or II, 45 right shoulders and 25 left shoulders), had subacute or chronic pain, fulfilled the selection criteria, agreed to participate, and signed informed consent statements were enrolled in the study (42 women and 28 men; mean age=54.1 years, SD=9.0, range=35-69; mean time since onset of pain=8.4 months, SD=9.8). These participants were randomly assigned to 2 groups: a group of 35 participants received HILT women and 15 men), and a group of 35 participants received US therapy (22 women and 13 men). Reasons

for exclusion are shown in the Figure, which is a flow diagram of participant recruitment and retention. No participant reported taking analgesic or anti-inflammatory drugs during the study. All 70 participants completed the trial and were included in the analysis.

Outcome Measures

All of the participants in the present study were evaluated with a visual analog scale (VAS),39 the Constant-Murley Scale (CMS), 40 and the Simple Shoulder Test (SST).41 The VAS is used to measure pain on a 10-cm horizontal axis between a left endpoint of "no shoulder pain" and a right endpoint of "worst pain ever." The distance is measured, and pain is recorded on a 10-point scale.39 In the acute pain setting, the VAS has been shown to have very good test-retest reliability (intraclass correlation coefficient [ICC] = .99)⁴²; this scale generally is accepted as a valid measure of acute pain, with good construct validity.43,44 At a recent consensus meeting of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), the results of several studies on this issue were considered. It was suggested that raw score changes of approximately one point or percentage changes of approximately 15% to 20% represent the minimal clinically important difference (MCID) for the VAS and other, similar numerical rating scales (0-10) for pain intensity.45

The CMS is a 100-point scoring system in which 35 points are derived from a patient's report of pain and function.40 The remaining 65 points are allocated to a quantitative assessment of ROM and strength (forcegenerating capacity). The self-report assessment includes a single item for pain (15 points) and 4 items for activities of daily living (work, 4 points; recreation, 4 points; sleep, 2 points; and ability to work at various levels, 10 points). The quantitative assess-



Figure

Flow diagram of recruitment and retention of participants with subacromial impingement syndrome for ultrasound therapy and high-intensity laser therapy.

ment includes ROM (forward elevation, 10 points; lateral elevation, 10 points; and internal rotation, 10 points) and power (scoring is based on the number of pounds of pull a patient can resist in abduction to a maximum of 25 points). 40 This tool has good psychometric properties; the

CMS score reflects shoulder function with accuracy, test-retest reliability (ICC=.80),⁴⁶ and reproducibility.⁴⁷ Unfortunately, to date, there are no studies providing data on the MCID for the CMS, despite the fact that for this tool, error estimates (95% confidence interval [CI] of the standard error of measurement [SEM]=

±17.7)⁴⁶ and responsiveness (standardized response mean=0.59),⁴⁸ that is, the ability of a measure to detect change over time, have been reported.

The SST is a series of 12 questions with dichotomous "yes" or "no" response options. One group of ques-

tions pertains to pain, and a second group of questions relates to function. Strength and ROM are not directly evaluated. A theoretical "normal" shoulder would result in a "yes" answer to all 12 questions. The goal of the SST is to compare pain and function before and after treatments.41 Content, criterion, and construct validity have been measured for the SST.49 Test-retest reliability (ICC=.99),50 internal consistency (Cronbach alpha=.85),51 error estimates (95% CI of the SEM= ± 22.8 , calculated from a converted score range of 0-100),51 and responsiveness (standardized response mean=0.82 and effect size=.83) have been reported for the SST. Unfortunately, at present, there are no data on the MCID for the SST.

Randomization

After the baseline examination, participants were randomly assigned to receive HILT or US therapy. Concealed allocation was performed with random numbers generated from the Web site http://www. random.org/ before the beginning of the study. The procedure Random Integer Generator allowed us to generate random integers. A priori it generated 100 random integers and, before the beginning of the study, the randomization number was already present. Individual, sequentially numbered index cards with the random assignments were prepared. The index cards were folded and placed in sealed opaque envelopes. A physician who was unaware of the baseline examination findings opened the envelopes to attribute the interventions according to the group assignments.

Interventions

The protocol involved the application of 2 different forms of physical therapy modalities for a total of 10 treatment sessions over a period of 2 consecutive weeks (5 days per week). A physiatrist (A.S.) with 6 years of experience provided HILT, and a physical therapist with 7 years of experience provided US therapy.

Participants in the HILT group received HILT with a neodymiumyttrium aluminum garnet laser that has a pulsating waveform produced by an HIRO 1.0 device (ASA srl*). The treatment consisted of a high peak power (1 kW), a wavelength of 1,064 nm, a maximum energy for a single impulse of 150 mJ, an average power of 6 W, a fluency of 760 mJ\cm², and a duration for the single impulse of less than 150 milliseconds. A pulsating waveform (5,000 W/cm²) can transfer 1,000 times more light intensity to the soft tissues than a continuous waveform (5 W/cm²) with the same average power (1 W) and bright spot (0.2 cm²). These ultrashort impulses established a deep action in biological tissue (3-4 cm), with a homogeneous distribution of the light source in the irradiated soft tissue but without excessive thermal enhancements. A standard handpiece endowed with fixed spacers was used to ensure the same distance to the skin and verticality of 90 degrees to the zone to be treated with a brightspot diameter of 5 mm. Three phases of treatment were performed for every session.

An initial phase involved fast manual scanning (100 cm²/30 s) of the zones of muscular contracture, particularly for the upper trapezius and deltoid muscles and anteriorly for the pectoralis minor muscle. Scanning was performed in both transverse and longitudinal directions with the arm positioned in internal rotation and extension to expose the rotator cuff. In this phase, a total energy dose of 1,000 J was administered.

An intermediate phase involved applying the handpiece with fixed

spacers vertically to 90 degrees on the trigger points until a pain reduction of 70% to 80% was achieved. In this phase, the mean energy dose was 50 J. A final phase involved slow manual scanning (100 cm²/60 s) of the same areas treated in the initial phase until a total energy dose of 1,000 J was achieved.

Three steps were predicted in the starting/initial and final phases of the treatment; the fluencies used were 510, 610, and 710 mJ/cm², respectively. Therefore, the total dose of energy administered was approximately 2,050 J. The time to apply all 3 stages of HILT was approximately 10 minutes.

Participants in the US therapy group received continuous US for 10 minutes with a SONOPLUS 492, a device that was operated at a frequency of 1 MHz, an intensity of 2 W/cm², and a duty cycle of 100%. The transducer head had an area of 5.8 cm² and an effective radiating area of 4.6 cm². The treating physical therapist, using the technique of slow circular movements, applied the transducer head over the superior and anterior periarticular regions of the participant's glenohumeral joint and on the shoulder trigger points, covering an area of approximately 20 cm² (4 times the effective radiating area). Participants were assessed by a physical medicine physician at the baseline (before the first treatment session) and at the end of physical therapy (after the last treatment session). Moreover, the pretreatment and posttreatment clinical evaluations (VAS, CMS, and SST) were done by the same tester. It is important to remember that the physicians who performed the clinical evaluations of the participants were unaware of the group assignments. All participants in the 2 treatment groups received

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Table 1.

Baseline Demographic and Clinical Characteristics of Participants With Subacromial Impingement Syndrome (SAIS) in High-Intensity Laser Therapy (HILT) and Ultrasound (US) Therapy Groups

Characteristic	HILT Group (n=35)	US Therapy Group (n=35)	P	
Age, y				
X (SD)	54.2 (8.2)	54.0 (9.8)	.93ª	
Range	38-69	35–69		
Time since onset of pain, mo				
X (SD)	8.7 (8.8)	8.1 (10.8)	.82 ^b	
Range	1–36	1-42		
Sex (female/male)	20/15	22/13	.63°	
Diagnosis (n)				
SAIS Neer stage I	13	14	.81°	
SAIS Neer stage II	22	21		

^a As determined by an independent 2-sample t test.

10 treatment sessions in the 2-week period.

Sample Size Determination

The sample size and power calculations were performed with nQuery Advisor statistical software (version 6.0). Sample sizes of 35 for the HILT group and 35 for the US therapy group achieved a power of 80% to detect a difference of 50% in the VAS (score=1.0 point) in a design with 2 repeated measurements when the standard deviation was 1.5, the correlation between observations for the same participant was .7, and the alpha level was .05.

Data Analysis

All analyses were performed with SAS statistical software (version 9.1). Frequency distributions as well as means and standard deviations were used for descriptive purposes. At the baseline, differences in age and time since the onset of pain between treatment groups were

analyzed with an independent 2-sample t test and a Mann-Whitney U test, respectively. Differences in sex and SAIS Neer stage frequency distributions were evaluated with a Pearson chi-square test. Differences between treatment groups in change scores at the baseline and after 10 treatment sessions over a period of 2 consecutive weeks were analyzed with an independent 2-sample t test. Repeated measurements obtained before and after treatments within groups were analyzed with a pairedmatched t test. A 2-way repeatedmeasures analysis of variance (ANOVA) was performed to estimate differences between (group effect) and within (time and time × group effects) treatment groups for each studied outcome. The statistical inferences were adjusted according to Bonferroni inequality (P values corresponding to .05/6 = .008 and .01/6=.002). The alpha level for significance was set at .05.

Role of the Funding Source

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Council-CNR-Targeted Project on Aging grants 9400419PF40 and 95973PF40). The funding agencies had no role in the design, conduct, or reporting of the study.

Results

Table 1 summarizes the baseline clinical and demographic characteristics of the subjects enrolled in the study. Table 2 summarizes test performance at the baseline and at the completion of the study (after 10 treatment sessions over a period of 2 consecutive weeks) for each treatment group. A significant change in test performance was observed in both groups after the initiation of treatments (VAS: ANOVA F statistic for a time effect=435.73; df=1,68; P<.001; CMS: ANOVA F statistic for a time effect=800.98; df=1,68; P < .001; SST: ANOVA F statistic for a time effect=366.38; df=1,68; P < .001). Moreover, we found a significant difference in VAS scores when we compared US therapy with HILT (ANOVA F statistic for groups=10.863, P=.002), but we found no significant differences in CMS and SST scores between treatments. Finally, statistically significant differences in changes from the baseline after 10 treatment sessions by treatment group were observed (VAS: ANOVA F statistic for a time \times group effect: 34.07; df = 1,68; P<.001; CMS: ANOVA F statistic for a time \times group effect=22.72; df=1,68; P<.001; SST: ANOVA Fstatistic for a time × group effect=7.88; df=1,68; P=.007).

Multiple comparisons analyzing differences within groups were performed for the HILT group and the US therapy group, and the results are shown in Table 2. Multiple comparisons analyzing differences between groups also are shown in Table 3. Finally, we analyzed differences in change scores between groups after 10 treatment sessions over a period of 2 consecutive weeks; we found

^b As determined by the Mann-Whitney *U* test.

^c As determined by the Pearson chi-square test.

^{*} Statistical Solutions Ltd, 7B Airport East Business Park, Farmer's Cross, Cork, Ireland (www.statsol.ie).

SAS Institute Inc, PO Box 8000, Cary, NC 27511.

Table 2.Test Performance at Baseline and After Intervention for Participants With Subacromial Impingement Syndrome in High-Intensity Laser Therapy (HILT) and Ultrasound (US) Therapy Groups: Evaluation Within Groups and Between Groups^a

Test	HILT Group (n=35)	US Therapy Group (n=35)	Mean Difference in Change Scores (95% CI)	Actual P Value	Bonferroni- Corrected P Value ^b
VAS score					
Baseline 6.28 (1.8)		6.6 (1.53)	0.29 (-1.10 to 0.52)	.48	NS
After intervention	2.42 (1.42)	4.44 (1.37)	-1.97 (-2.64 to -1.30)	<.001	<.01
Mean difference in change scores (95% CI)	3.86 (3.33 to 4.39)	2.17 (1.92 to 2.43)			
Actual P value	<.001	<.001			
Bonferroni-corrected <i>P</i> value ^b	<.01	<.01			_
CMS score					
Baseline	63.22 (8.68)	63.08 (7.05)	0.14 (-3.63 to 3.92)	.94	NS
After intervention	75.91 (7.02)	72.11 (6.95)	0.14 (-3.63 to 3.92)	.03	NS
Mean difference in change scores (95% CI)	-12.69 (-13.94 to -11.43)	-9.03 (-9.96 to -8.10)		***	-
Actual P value	<.001	<.001			
Bonferroni-corrected P value ^b	<.01	<.01		-	
SST score					
Baseline	7.22 (2.28)	6.91 (2.24)	0.31 (-0.77 to 1.39)	.56	NS
After intervention	9.68 (1.99)	8.74 (2.04)	0.94 (-0.02 to 1.91)	.06	NS
Mean difference in change scores (95% CI)	-2.46 (-2.86 to -2.06)	-1.83 (-2.04 to -1.62)			
Actual P value	<.001	<.001			
Bonferroni-corrected P value ^b	<.01	<.01			

^o Values are means (SDs) unless otherwise indicated. CI=confidence interval, VAS=visual analog scale, NS=not significant, CMS=Constant-Murley Scale, SST=Simple Shoulder Test.

statistically significant differences for VAS, CMS, and SST scores (Tab. 3).

Discussion

In the present study, we compared the results obtained after 10 treatment sessions over a period of 2 consecutive weeks with 2 different physical therapy modalities in subjects diagnosed with Neer stage I or II SAIS. The subjects treated with HILT showed a greater reduction in pain and more improvement in articular movement, functionality, and muscle strength of the affected shoulder than the subjects treated

with US therapy (as measured with the VAS, CMS, and SST). Significant differences in changes after 10 treatment sessions over a period of 2 consecutive weeks from the baseline by treatment group were observed. In particular, the difference in the change in the VAS scores between the groups (1.65 points) surpassed the accepted MCID for this tool.⁴⁷

Contrasting findings have been reported for US therapy and laser therapy in the treatment of SAIS and other shoulder disorders. 11-21 There is little evidence that active thera-

peutic US is more effective than placebo US for treating people with soft-tissue disorders of the shoulder, including SAIS.17,20,21 Several authors^{20,52,53} have reported no differences between true US and sham US for subjects with soft-tissue disorders of the shoulder. Conversely, studies by other researchers have supported the efficacy of US therapy in reducing pain, improving activities of daily living, and improving quality of life.26,27 In particular, Ebenbichler and colleagues²⁷ reported that 24 daily applications of US therapy at 2.5 W/cm² (5 times per week for 3

^b The statistical inferences were adjusted according to Bonferroni inequality within groups.

Table 3.

Change in Test Performance Over Time From Baseline for Participants With Subacromial Impingement Syndrome in High-Intensity Laser Therapy (HILT) and Ultrasound (US) Therapy Groups: Evaluation Between Groups

Variable	Both Groups (N=170)	HILT Group (n=35)	US Therapy Group (n=35)	Difference in Means (95% CI)	Actual P Value	Bonferroni-Corrected P Value ^b
VAS score						
X (SD)	-3.01 (1.46)	-3.86 (1.53)	-2.17 (0.75)	-1.69 (-2.27 to -1.12)	<.001	· <.01
%	-48.89	-61.36	-33.04			
CMS score						
·X (SD)	10.86 (3.68)	12.69 (3.64)	9.03 (2.70)	3.66 (2.13 to 5.19)	<.001	<.01
%	17 19	20.06	14.31			
SST score						
X (SD)	2.14 (0.98)	2.46 (1.17)	1.83 (0.61)	0.63 (0.18 to 1.08)	.006	<.05
%	30 30	33.99	26.45			

CI=confidence interval, VAS=visual analog scale, CMS=Constant-Murley Scale, SST=Simple Shoulder Test.

weeks and then 3 times per week for 3 weeks) reduced the painful symptoms in patients with calcific tendinitis of the supraspinatus tendon; in addition, the calcium deposits resolved in 19% of patients in the US therapy group and decreased by at least 50% in 28% of the patients. The variability of shoulder disorders and variations in the treatment intensity, duration, frequency, and location of US applications in previous studies could explain, in part, these contrasting findings. ^{20,26,27,52,53}

Some authors^{20,31,32,34} have suggested that LILT used without other physical therapy modalities could be helpful in the management of SAIS. For a small group of patients with tendinitis of the supraspinatus tendon, the data revealed that the patients treated with LILT had less pain, less secondary weakness, and less tenderness after the treatment than before.32 However, in another study of patients with shoulder tendonitis, LILT had only a short-term benefit for pain, self-reported function, active ROM, stiffness, and restriction after 2 weeks of treatment when compared with a placebo laser.34 Furthermore conflicting results were demonstrated by Vecchio and colleagues³⁵ in a comparison of patients who had SAIS and were treated with LILT and ROM exercises and patients who were treated with a placebo laser and ROM exercises; at 4- and 8-week follow-up sessions, there was no difference between groups with regard to pain, ROM, function, or strength. A recent metaanalysis suggested analgesic and tissue repair actions of LILT,33 whereas another study reported that 10 applications of LILT for 2 weeks did not induce significant pain relief and improvements in articular function relative to the findings for a group control given a placebo.54 Therefore, although the current evidence is conflicting, it appears that LILT was more beneficial than a placebo when applied as a single intervention for participants with SAIS.

Our findings with HILT may lead to promising new therapeutic options. In the present study, the results obtained after 10 treatment sessions with the experimental protocol suggested greater effectiveness of HILT than of US therapy in the treatment of SAIS. The participants treated with HILT showed a greater reduction in pain and more improvement in articular movement, functionality,

and muscle strength of the affected shoulder than the participants treated with US therapy. No studies have yet been conducted to compare the effectiveness of these different physical therapies, but no therapeutic differences among US therapy, LILT, and combined treatments were noted for tendon healing in rats.⁵⁵

High-intensity laser therapy quickly reduces inflammation and painful symptoms.⁵⁶ It utilizes a particular waveform with regular peaks of elevated values of amplitude and distances (in time) between them to decrease thermal accumulation phenomena, and it is able to rapidly induce in the deep tissue photochemical and photothermic effects that increase blood flow, vascular permeability, and cell metabolism.⁵⁷ The HILT had an analgesic effect on nerve endings, but there was no evidence of a diminution inflammation.58,59

Limitations of the present study include the lack of a control group receiving no treatment; this limitation constrains our ability to claim cause and effect. Participants in both groups may have improved simply because of the passage of time and

^b The statistical inferences were adjusted according to Bonferroni inequality (0.05/6=0.008 and 0.01/6=0.002).

the avoidance of strenuous activity for the treatment period. We have compared a new treatment option (HILT) with an accepted physical therapy modality, US therapy. As discussed above, some studies have shown US therapy to be effective in improving symptoms^{26,27} and have proposed this treatment as an acceptable physical therapy modality for SAIS.16 Additionally, the fact that the participants in one group were treated by a physical therapist and the participants in another group were treated by a physiatrist is a limitation of the present study because the participants were randomly assigned to physiatrist-HILT or physical therapist-US therapy groups. Another limitation is the lack of follow-up data, which reduces the clinical application of our findings on the short-term effects of HILT and US therapy in SAIS. Furthermore, our protocol of 10 treatment sessions over a period of 2 weeks could be challenging to apply in clinical practice. Finally, notwithstanding the good psychometric properties of the 3 measurement tools used in the present study, we only have MCID data on the VAS, limiting our ability to attribute a clinical significance to the differences between groups observed with the CMS and the SST. However, the difference in the change in the VAS scores between the groups (1.65 points) surpassed the MCID for this tool.45 On the other hand, the 95% CI of the SEM for the CMS was ± 17.7 points, 46 and the between-group difference did not surpass the SEM (3.8 points). Moreover, although the reliability of the SST has been reported to be good,60 a recent psychometric evaluation of the CMS suggested that its use is acceptable when pretreatment and posttreatment scores are determined by the same tester,54 as in the present study.

Conclusion

Although further studies are needed to confirm the effectiveness of physical therapy interventions for SAIS, HILT was shown to have greater benefit for SAIS than US therapy in reducing pain and improving the articular movement, functionality, and muscle strength of the affected shoulder. The results of the present study are encouraging, but other studies with larger samples, longerterm findings, and possible comparisons with other conservative interventions or placebo control groups are needed.

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References

- 1 Flatow EL, Soslowsky LJ, Ticker JB, et al. Excursion of the rotator cuff under the acromion: patterns of subacromial contact. Am J Sports Med. 1994;22:779-784.
- 2 Bigliani LU, Morrison DS, April EW. The morphology of the acromion and its relationship to rotator cuff tears. Orthop Trans. 1986;10:228-234.
- 3 Gerber C, Schneeberger AG, Vinh TS. The arterial vascularization of the humeral head: an anatomical study. J Bone Joint Surg Am. 1990;72:1486-1494
- 4 Rothman RH, Parke WW. The vascular anatomy of the rotator cuff. Clin Orthop Relat Res. 1965;41:176-186.

- 5 Rathbun JB, Macnab I. The microvascular pattern of the rotator cuff. I Bone Joint Surg Br. 1970;52:540-553.
- 6 Itoi E, Berglund LJ, Grabowski JJ, et al. Tensile properties of the supraspinatus tendon. J Orthop Res. 1995;13:578-584.
- 7 Neér CS II. Impingement lesions. Clin Orthop Relat Res. 1983;173:70-77
- 8 Neer CS II. Shoulder Reconstruction, Philadelphia, PA: WB Saunders; 1990:41-142.
- 9 Bertin P, Behier JM, Noel E, Leroux JL. Celecoxib is as efficacious as naproxen in the management of acute shoulder pain. J Int Med Res. 2003;31:102-112.
- 10 Blair B, Rokito AS, Cuomo F, et al. Efficacy of injections of corticosteroids for subacromial impingement syndrome. J Bone Joint Surg Am. 1996;78:1685-1689
- 11 Senbursa G, Baltaci G, Atay A. Comparison of conservative treatment with and without manual physical therapy for patients with shoulder impingement syndrome: a prospective, randomized clinical trial. Knee Surg Sports Traumatol Artbrosc. 2007;15:915-921.
- 12 Binder A, Hodge G, Greenwood AM, et al. Is therapeutic ultrasound effective in treating soft tissue lesions? BMJ. 1985;290: 512-514.
- 13 van der Heijden GJ, van der Windt DA, de Winter AF Physiotherapy for patients with soft tissue shoulder disorders: a systematic review of randomised clinical trials. BMJ. 1997;315:25-30.
- 14 van der Windt DA, van der Heijden GJ, van den Berg SG, et al. Ultrasound therapy for musculoskeletal disorders: a systematic review. Pain. 1999;81:257-271.
- 15 van der Heijden GJ. Shoulder disorders: a state-of-the-art review. Baillieres Best Pract Res Clin Rheumatol. 1999;13: 287-309.
- 16 Philadelphia Panel. Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions for shoulder pain. Phys Ther. 2001;81: 1719-1730.
- 17 Robertson VJ, Baker KG. A review of therapeutic ultrasound: effectiveness studies. Phys Ther. 2001;81:1339-1350.
- 18 Desmeules F, Cote CH, Fremont P. Therapeutic exercise and orthopedic manual therapy for impingement syndrome: a sys tematic review Clin J Sports Med. 2003;13:176-182.
- 19 Green S, Buchbinder R, Hetrick S. Physiotherapy interventions for shoulder pain. Cochrane Database Syst Rev. 2003; CD004258
- 20 Michener LA, Walsworth MK, Burnet EN. Effectiveness of rehabilitation for patients with subacromial impingement syndrome: systematic review. J Hand Ther. 2004;17:152-164.
- 21 Faber E, Kuiper JI, Burdorf A, et al. Treatment of impingement syndrome: a systematic review of the effects on functional limitations and return to work. J Occup Rehabil. 2006;16:7-25.

- 22 Kuhn JE. Exercise in the treatment of rotator cuff impingement: a systematic review and a synthesized evidence-based rehabilitation protocol. J Shoulder Elbow Surg. 2009;18:138-160.
- 23 Maxwell L. Therapeutic ultrasound: its effects on the cellular and molecular mechanisms of inflammation and repair. *Physiotherapy*. 1992;78:421-426.
- 24 Grant HJ, Arthur A, Pichora DR. Evaluation of interventions for rotator cuff pathology: a systematic review. *J Hand Ther*. 2004;17:274-299.
- 25 Neer CS II. Anterior acromioplasty for the chronic impingement syndrome in the shoulder: a preliminary report. *J Bone Joint Surg Am.* 1972;54:41-50.
- 26 Mao CY, Jaw WC, Cheng HC. Frozen shoulder: correlation between the response to physical therapy and follow-up shoulder arthrography. Arch Phys Med Rebabil. 1997;78:857–859.
- 27 Ebenbichler GR, Erdogmus CB, Resch KL, et al. Ultrasound therapy for calcific tendinitis of the shoulder. *N Engl J Med*. 1999;340:1533-1538
- 28 Basford JR. Low intensity laser therapy: still not an established clinical tool. *Lasers Surg Med.* 1995;16:331-342.
- 29 Ohshiro T, Calderhead R. Development of low reactive-level laser therapy and its present status. *J Clin Laser Med Surg.* 1991;9:267-275.
- 30 Zati A, Valent A. Laserterapia in medicina. In: Terapia Fisica: Nuove Tecnologie in Medicina Riabilitativa. Edizioni Minerva Medica; 2006:162-185.
- 31 Sauers EL. Effectiveness of rehabilitation for patients with subacromial impingement syndrome. *J Athl Train*. 2005;40: 221-223.
- 32 Saunders L. The efficacy of low level laser therapy in supraspinatus tendonitis. Clin Rebabil. 1995;9:126 1134.
- 33 Enwemeka CS, Parker JC, Dowdy DS, et al. The efficacy of low-power laser in tissue repair and pain control: a meta-analysis study. *Photomed Laser Surg.* 2004;22: 323–329.
- 34 England S, Farrell AJ, Coppock JS, et al. Low power laser therapy of shoulder tendonitis. *Scand J Rheumatol.* 1989;18: 427-431.
- 35 Vecchio P, Cave M, King V, et al. A doubleblind study of the effectiveness of low level laser treatment of rotator cuff tendinitis. *Br J Rheumatol*. 1993;32:740-742.
- 36 Berry H, Fernandes L Bloom B, et al. Clinical study comparing acupuncture, physiotherapy, injection and oral anti-inflammatory therapy in shoulder-cuff lesions. Curr Med Res Opin. 1980;7: 121-126.

- 37 Hawkins RJ, Kennedy JC. Impingement syndrome in athletes. *Am J Sports Med*. 1980;8:151-158.
- 38 Naredo E, Aguado P, Miguel E, et al. Painful shoulder: comparison of physical examination and ultrasonographic findings. *Ann Rheum Dis.* 2002;61:132-136.
- 39 Price DD, Bush FM, Long S, et al. A comparison of pain measurement characteristics of mechanical visual analogue and simple numerical rating scales. *Pain*. 1994;56:217–226.
- 40 Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res. 1987;Jan:160-164.
- 41 Lippitt SB, Harryman DT, Matsen FA. A practical tool for evaluating function: the Simple Shoulder Test. In: Matsen FA, Fu FH, Hawkins RJ, eds. *The Shoulder: A Balance of Mobility and Stability*. Rosemont, IL: American Academy of Orthopedic Surgeons; 1993:501–530.
- 42 Bijur PE, Latimer CT, Gallagher EJ. Validation of a verbally administered numerical rating scale of acute pain for use in the emergency department. *Acad Emerg Med*. 2003;10:390-392.
- 43 Jensen MP, Karoly P, Braver S. The measurement of clinical pain intensity: a comparison of six methods. *Pain*. 1986; 27:117-126.
- 44 Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. *J Clin Nurs*. 2005;14:798–804.
- 45 Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. 2008;9:105-121.
- 46 Conboy VB, Morris RW, Kiss J, Carr AJ. An evaluation of the Constant-Murley shoulder assessment. *J Bone Joint Surg Br*. 1996;78:229–232.
- 47 Gazielly F, Gleyze P, Mantangnon C. Functional and anatomical results after rotator cuff repair. Clin Orthop Relat Res. 1994;304:43-53.
- 48 Kirkley A, Griffin S, McLintock H, Ng L. The development and evaluation of a disease-specific quality of life measurement tool for shoulder instability: the Western Ontario Shoulder Instability Index (WOSI). Am J Sports Med. 1998;26:764-772.
- 49 Godfrey J, Hamman R, Lowenstein S, et al. Reliability, validity, and responsiveness of the Simple Shoulder Test: psychometric properties by age and injury type. J Shoulder Elbow Surg. 2007;16:260-267.

- 50 Beaton DE, Richards RR. Assessing the reliability and responsiveness of 5 shoulder questionnaires. J Shoulder Elbow Surg. 1998;7:565-572.
- 51 Roddey TS, Olson SL, Cook KF, et al. Comparison of the University of California-Los Angeles Shoulder Scale and the Simple Shoulder Test with the shoulder pain and disability index: single-administration reliability and validity. *Phys Ther.* 2000;80: 759-768.
- 52 Nykanen M. Pulsed ultrasound treatment of the painful shoulder: a randomized, double-blind, placebo-controlled study. *Scand J Rebabil Med.* 1995;27:105–108.
- 53 Kurtaiş Gürsel Y, Ulus Y, Bilgiç A, et al. Adding ultrasound in the management of soft-tissue disorders of the shoulder: a randomized placebo-controlled trial. *Phys Ther.* 2004;84:336–343.
- 54 Bingol U, Altan L, Yurtkuran M. Low-power laser treatment for shoulder pain. Photomed Laser Surg. 2005;23:459 - 464.
- 55 Demir H, Menku P, Kirnap M, et al. Comparison of the effects of laser, ultrasound, and combined laser + ultrasound treatments in experimental tendon healing. *Lasers Surg Med.* 2004;35:84-89.
- 56 Zati A, Degli Esposti S, Bilotta TW. Il laser CO₂: effetti analgesici e psicologici in uno studio controllato. *Laser & Technology*. 1997;7:723-730.
- 57 Kujawa J, Zavodnik L, Zavodnik I, et al. Effect of low-intensity (3.75-25 J/cm²) near-infrared (810 nm) laser radiation on red blood cell ATPase activities and membrane structure. J Clin Laser Med Surg. 2004;22:111-117.
- 58 Tsukya K, Kawatani M, Takeshige C, et al. Laser irradiation abates neuronal responses to nociceptive stimulation of rat-paw skin. *Brain Res Bull*. 1994;34: 369-374.
- 59 Nicolau RA, Martinez MS, Rigau J, Tomàs J. Neurotransmitter release changes induced by low power 830 nm diode laser irradiation on the neuromuscular junctions of the mouse. Lasers Surg Med. 2004;35:236-241.
- 60 Rocourt MH, Radlinger L, Kalberer F, et al. Evaluation of intratester and intertester reliability of the Constant-Murley shoulder assessment. *J Shoulder Elbow Surg.* 2008; 17:364-369.

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