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Original article

Short-term effects of high-intensity laser therapy on frozen shoulder: A prospective randomized control study

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ABSTRACT

Background: Frozen shoulder, which is characterized by shoulder pain and limitation of the range of motion (ROM), is a common disorder. High-intensity laser therapy (HILT) was recently introduced in the musculoskeletal therapeutic field.
Objective: The objective of this study is to evaluate the clinical efficacy of HILT in patients with frozen shoulder.
Design: A prospective randomized controlled study.
Method: Patients with frozen shoulder were randomly divided into 2 groups: a HILT group ($n = 33$) and a placebo group ($n = 33$). The treatment was administered 3 times per week on alternate days for 3 weeks. For all patients, the visual analog scale (VAS) for pain, VAS for satisfaction, and passive ROM were measured at baseline and 3, 8, and 12 weeks after the treatment.
Results: The HILT group had a lower pain VAS score at 3 weeks (3.2 ± 1.7 vs. 4.3 ± 2.2, $p = 0.033$) and 8 weeks (2.2 ± 2.0 vs. 3.4 ± 2.7, $p = 0.042$), however, no statistically significant difference in the pain VAS was observed between the two groups at the final follow-up (12 weeks). No statistical difference in the ROM and the satisfaction VAS was observed between the 2 groups at serial follow-ups.
Conclusions: In management of frozen shoulder, HILT provided significant pain relief at 3 and 8 weeks, but not at the final follow-up time point. HILT is a noninvasive adjuvant treatment that can reduce pain in frozen shoulders. Further study is needed in order to optimize the dose and duration of HILT.

1. Introduction

Frozen shoulder is one of the most common causes of shoulder pain and disability, with a prevalence of 2–5% among the general population (Bunker, 1997; Hannafin and Chiaia, 2000; Lewis, 2015). It is characterized by shoulder pain and limitation in range of motion (ROM) (Neviaser and Hannafin, 2010). Many studies have attempted to determine the pathophysiology of frozen shoulder and the best treatment modality (Bunker et al., 2000; Uhthoff and Boileau, 2007; Tamai et al., 2014). Fibrosis and contracture of the joint capsule, preceded by synovitis are known symptoms of frozen shoulder. However, the initiator of synovitis remains unclear (Lewis, 2015).

Several approaches have been used successfully for management of frozen shoulder. These include medical treatment (Buchbinder et al., 2004), physical therapy and exercise (Griggs et al., 2000; Levine et al., 2007), intra-articular steroid injections (Ryans et al., 2005), hydraulic distension (Buchbinder and Green, 2004), blockade of the suprascapular nerve (Dahan et al., 2000), manipulation under anesthesia (Farrell et al., 2005), arthroscopic release (Le Lievre and Murrell, 2012), and skillful neglect (Diercks and Stevens, 2004). The main goal in all types of treatment of frozen shoulder is regaining the ROM and pain management. Traditionally, gentle passive stretching exercise with pain management is one of the basic treatment options (Griggs et al., 2000; Kivimaki et al., 2007; Levine et al., 2007; Marinko et al., 2011; Donatelli et al., 2014).

There are numerous adjuvant treatments to exercise therapy in order to help the patient regain ROM and restore function to the affected shoulder (Cheing et al., 2008; Chen et al., 2014; Desmeules et al., in press; Green et al., 2003; Guyver et al., 2014; Page et al., 2014a; Sun et al., 2001; Van der Heijden et al., 1999). Among adjuvant treatments, low-intensity lasers were employed in the early days of laser therapy and, recently, high-intensity laser therapy

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(HILT) has been introduced and used in musculoskeletal disorders (Santamato et al., 2009; Fiore et al., 2011; Štiglić-Rogoznica et al., 2011; Zati et al., 2012; Alayat et al., 2014; Dundar et al., in press; Kheshie et al., 2014). Currently, there is no universally accepted theory that explains the mechanism of the postulated laser effects (Knappe et al., 2004; Quinto-Su and Venugopalan, 2007; Oliveira et al., 2012). However, it is postulated that there are three types of laser tissue interaction that can be distinguished: photochemical effects, photothermal effects, and photomechanical/photoionizing effects (Knappe et al., 2004). In HILT, an Nd:YAG laser is employed. The laser has a wavelength of 1064 nm which causes minor and slow light absorption by chromophores and delivers radiation non-invasively to deep tissue to ensure treatment efficacy (Basford, 1995). In addition to having a higher power than low-intensity lasers, lasers used in HILT have a shorter laser emission time and a longer laser emission interval (low duty cycle). Therefore, a large amount of laser irradiation can be delivered to deep tissues (Zati and Valent, 2006; Santamato et al., 2009).

The primary purpose of this study was to compare the respective pain levels at different intervals between HILT and placebo control in patients with frozen shoulder using a prospective randomized comparison model. In addition, range of motion and satisfaction were also compared. The null hypothesis of the study was that pain levels would not differ between the two groups during follow-up at each time point.

2. Materials and methods

2.1. Inclusion and exclusion criteria

A prospective randomized controlled study was conducted after obtaining approval from the Institutional Review Board of the authors' institution (1303-020-471). Written informed consent was obtained from all patients participating in the study.

Sample size analysis was performed prior to the study based on the visual analogue scale (VAS) for pain, which was the primary outcome of the study. In our previous patients' data pool, the pain VAS of patients with frozen shoulder showed a normal distribution, with a standard deviation of 2. After setting the mean difference at a 1.5 scale (0.75, moderate to large effect size according to Cohen's d) in the experimental and control group, 29 subjects in each group were required to be able to reject the null hypothesis (power = 0.8, type I error = 0.05). Considering a dropout rate of 10%, a total of 66 patients were required.

The set criteria for inclusion was shoulder pain for at least 1 month prior to presentation at the clinic and limitation of passive movement of the shoulder joint compared to the contralateral asymptomatic shoulder (difference in forward flexion [FF]: 40°, external rotation at side [ER]: 20°, and internal rotation at back [IR]: 5 spine level). All patients underwent radiography (shoulder true anteroposterior view, 30° caudal tilt, and axial view) to rule out any bony abnormality, calcific tendinitis, and osteoarthritis. Patients with bilateral shoulder involvement, photoallergy, arthritic shoulder, calcific tendinitis, substantial trauma history, previous shoulder surgery, infection, rheumatoid arthritis, radiculopathy, and/or reflex sympathetic dystrophy were excluded from this study.

The patients were randomly (permuted-block randomization) allocated to either the HILT group or the placebo group (Fig. 1). Statistical analysis showed no difference in demographics between the groups (Table 1).

2.2. Treatment procedure

After allocation, the HILT group had 9 treatment sessions over 3 consecutive weeks (3 times per week on alternating days). The procedure was performed by a physical therapist with experience using a HILT machine (Hilthera®, Jeisys, Seoul, Korea). The device emits a wavelength of 1064 nm (Nd:YAG laser) and high-peak power (8000 W) laser for a short on time (120–150 μs), and provides enough thermal relaxation time to reduce the danger of burns.

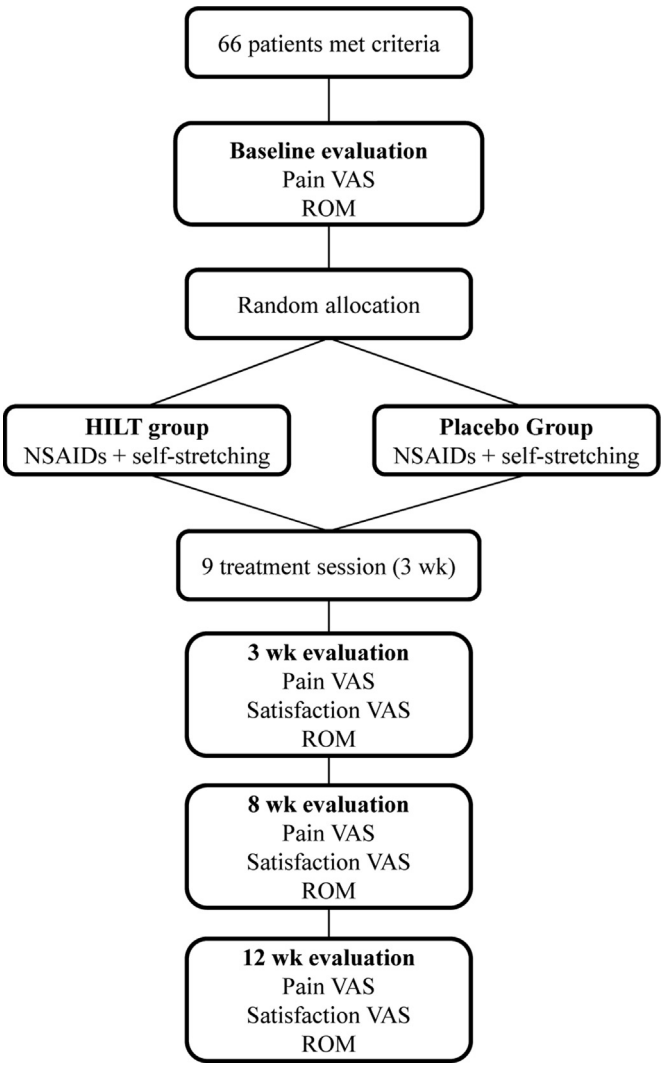

Fig. 1. Study design. VAS: visual analogue scale; ROM: range of motion; HILT: high-intensity laser therapy; NSAID: nonsteroidal anti-inflammatory drug.

The treatment consisted of 3 phases in each session (Fig. 2). The initial phase involved rapid manual scanning (100 cm^2/30 s) of the anterior joint line and posterior joint line of the shoulder with one shot of 850 mJ at a frequency of 30 Hz. The scanning was performed

Table 1
Demographics of both groups.

Demographics	HILT (n = 33)	Placebo (n = 33)	P value
Age (yr)	57.5 ± 8.7 (range, 41–71)	55.6 ± 7.9 (range, 34–72)	0.344
Gender (M:F)	28: 5	26: 7	0.523
Dominant side involvement	14	17	0.459
Duration of symptom (mo)	6.0 ± 4.9	4.6 ± 2.7	0.138
Diabetes mellitus	3	4	0.689

Data represent the mean ± SD or absolute number.
HILT = high-intensity laser therapy.

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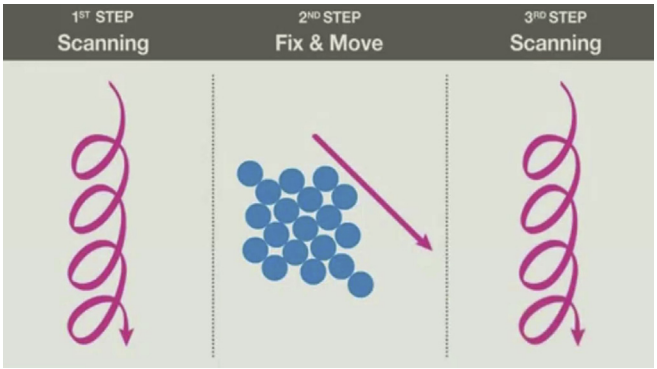

Fig. 2. Schematic drawing of a probe movement during 3 phases.

parallel to the joint line, with the patient's arm internally rotated on the posterior scan and externally rotated on the anterior scan. The total energy dose administered during this phase was 4000 J. The intermediate phase was a fixed scan phase, with one-shot emission of 350 mJ at a frequency of 20–25 Hz. The total delivered energy was 4000 J. In this phase, the hand piece was applied vertically perpendicular to the shoulder joint for 5 s. In each scan, the scanning points included both the anterior and posterior joint line of the shoulder. The final phase involved rapid manual scanning of the same areas treated in the initial phase and the deltoid area until a total energy dose of 2000 J. Application of all 3 stages of HILT took approximately 15 min. A standard hand piece equipped with a fixed spacer was used to ensure the same distance to the skin (Fig. 3). Both the subject and the operator wore protective goggles throughout the procedure to shield their eyes from the laser. The patients were encouraged to exercise between sessions.

Subjects in both the HILT and the placebo group were blind to their respective group placement. Subjects in the placebo group also wore protective goggles, and the HILT machine was operated in a fake-mode, which made the same noise and had the same audio guidance as the real procedure. All procedures were the same as those applied in the HILT group, except that no laser energy was emitted during the 9 sessions.

Fig. 3. During the treatment, laser emission was performed parallel to the joint line with a hand piece held in a vertical position. The fixed spacer ensured constant distance between the skin and light source.

Regardless of group allocation, all of the patients were prescribed the same nonsteroidal anti-inflammatory drugs (NSAIDs), and were provided with a self-exercise regimen consisting of gentle active-assistive or passive FF, abduction, external rotation, cross body adduction, and sleeper's stretch exercises. The patients were instructed to repeat the exercises slowly 10 times, 3–5 times each day, with the positions held for 5–10 s each time (Griggs et al., 2000). They were advised to stretch their shoulder to a point just above their limit of tolerance and to avoid strengthening exercises until the final follow-up. In both groups, the intake of NSAIDs was not strictly regulated. Patients were allowed to skip or stop medication, if the pain was tolerable or any side-effects occurred. Subjects were closely monitored for follow-up and those who completed all 9 treatment sessions and returned for a follow-up visit received a $100 remuneration fee.

2.3. Outcome measurement

All data (baseline and 3, 8, and 12 weeks) were prospectively collected by a clinical researcher who was blind to the study. The initial evaluation included obtaining a detailed medical history, including that of shoulder pain. The pain VAS was the primary result evaluated at each point of the study. The satisfaction VAS, passive ROM of FF, ER, and IR were also evaluated as secondary results at each point of the study. To evaluate the blindness of the study, the patients were asked at the end of the study (12 weeks) to guess the group to which they had been assigned.

To indicate their level of pain, the patients used a specially designed pain VAS ruler that allowed them to place an indicator at 10 cm intervals. The patients could not see the actual score marked on the other side. Pain VAS was measured after instructing patients to actively move their affected arm (forward elevation, abduction and reach object behind the back) and asking, "How much pain do you feel with these activities?" The VAS was scored on a scale of 0–10, with 10 indicating the highest level of pain. The satisfaction VAS was also measured by asking the subjects to rate their satisfaction by placing an indicator at 10 cm intervals on the same scale. Researchers then convert the values to a 100-point scale.

Passive ROM was measured using a goniometer with the patient's spine in a straight position. Passive FF was measured in degrees between the patient's arm and thorax on the scapular plane. Passive ER was measured in degrees between the thorax and forearm, with the patient's arm in an adducted position and the elbow flexed to 90°. Passive IR was measured according to the vertebral level reached with the tip of the thumb. The vertebral level was numbered serially as follows: 12 for the 12th thoracic vertebra, 13 for the 1st lumbar vertebra, 17 for the 5th lumbar vertebra, and 18 for any level below the sacral region (Oh et al., 2008).

2.4. Statistics

Statistical analysis was performed using SPSS software package (version 21.0, IBM SPSS statistics, Chicago, IL). Comparison of the demographic data of the groups was performed using a Student's *t*-test and a chi-square test. A paired *t*-test and a Student's *t*-test were used for inter- and intra-group comparisons of the outcome variables at each time point. The differences in the outcome values between the 2 groups according to the time points were also analyzed using a repeated-measures analysis of variance (RM ANOVA). Statistical significance was defined as a *P* value less than 0.05.

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3. Results

There was no follow-up loss or missing data throughout the study. There were no complications in either group. In the HILT group, some patients noticed warmth in the shoulder. However, none of the patients experienced any pain during treatment. Some patients in the placebo group also mentioned warmth of the treated area during the procedure. When the patients were asked which group they thought they had been assigned to, 21 patients in the HILT group and 18 in the placebo group believed themselves to be in the treatment (HILT) group. Therefore, blinding in the study was well maintained ($P = 0.453$).

The baseline pain VAS was not statistically different between the two groups, and the pain VAS showed continuous improvement throughout the follow-up period in both groups (Table 2 and Fig. 4). Between the final follow-up and baseline, statistically significant improvements in the pain VAS were observed in both groups (both Ps < 0.001). Both groups showed reductions in the pain VAS over time. However, at 3 and 8 weeks, significantly lower pain VAS was observed in the HILT group than in the placebo group in the RM ANOVA ($P = 0.033$). However, no statistically significant differences in the pain VAS were observed between groups at 12 weeks (final follow-up).

Regarding the secondary outcomes, the ROM (FF, ER, and IR) improved over time within the groups, and there were no statistically significant differences in the ROM between the groups (Table 2 and Figs. 5–7). There were also no statistically significant inter-group differences in satisfaction with the procedure at any given time (Table 2 and Fig. 8).

The total amount of medication intake did not differ between groups (12.1 ± 17.1 days in the HILT group vs 16.9 ± 18.6 days in the placebo group, $P = 0.284$). The number of patients who received steroid injections after evaluation at the final follow-up was statistically insignificant ($P = 1.000$, 5 in the HILT group and 4 in the placebo group).

4. Discussion

The current prospective randomized comparison study showed that HILT accompanied by stretching exercises decreased pain in frozen shoulder compared to a placebo control. Although there was no inter-group difference in the pain VAS at the final follow-up (12 weeks), the pain VAS of the HILT group was significantly lower at the end of the treatment period (3 weeks) and early follow-up period (8 weeks). However, no differences in the secondary outcomes (ROMs and satisfaction VAS) were observed at any given time during the follow-up.

The etiology of pain reduction in laser therapy is not clearly understood, and most studies focusing on this issue have been based on low-intensity laser therapy (Chow et al., 2009). Suggested mechanisms of pain reduction are a reduction in specific inflammatory markers (Albertini et al., 2004; Bjordal et al., 2006; Aimbire et al., 2007), neural blockade (Kudoh et al., 1989; Chow et al., 2007), oxidative stress, and muscle fatigue (Lopes-Martins et al., 2006; Leal Junior et al., 2008).

Table 2
Results of outcome variables.

Outcome variables	HILT ($n = 33$)	Placebo ($n = 33$)	P value
Pain VAS			
Baseline	6.2 ± 1.7	6.6 ± 1.8	0.358
3 wk	3.2 ± 1.7	4.3 ± 2.2	0.033
8 wk	2.2 ± 2.0	3.4 ± 2.7	0.042
12 wk (final)	2.0 ± 2.2	2.2 ± 2.2	0.619
Forward Flexion			
Baseline	121° ± 15°	119° ± 17°	0.653
3 wk	137° ± 14°	137° ± 14°	0.855
8 wk	145° ± 13°	143° ± 14°	0.645
12 wk (final)	150° ± 12°	150° ± 11°	0.838
External rotation at side			
Baseline	35° ± 9°	34° ± 12°	0.546
3 wk	46° ± 14°	47° ± 15°	0.748
8 wk	47° ± 15°	51° ± 12°	0.278
12 wk (final)	48° ± 14°	53° ± 13°	0.222
Internal rotation at back (spine level reached)			
Baseline	15.6 ± 2.5	15.9 ± 3.0	0.654
3 wk	13.0 ± 2.9	13.2 ± 3.0	0.835
8 wk	12.3 ± 2.7	12.2 ± 2.9	0.862
12 wk (final)	11.2 ± 2.3	11.3 ± 3.0	0.855
Satisfaction			
3 wk	65.2 ± 18.8	68.6 ± 22.9	0.501
8 wk	64.2 ± 30.9	69.9 ± 23.3	0.403
12 wk (final)	74.2 ± 23.6	81.0 ± 17.1	0.181

Data represent the mean ± SD.

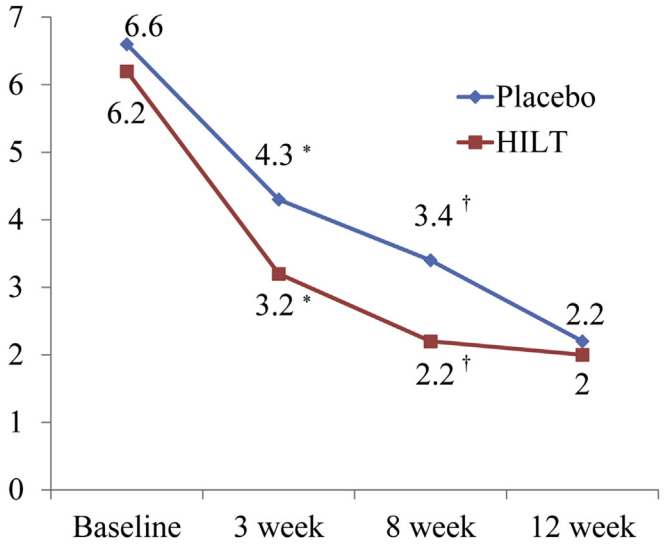

Fig. 4. Improvement in pain visual analogue scale (VAS) according to the follow-up periods. Statistically significant differences were observed between the two groups immediately after the treatment session (3 weeks) and at 8 weeks. *, †$P < 0.05$, HILT: high-intensity laser therapy.

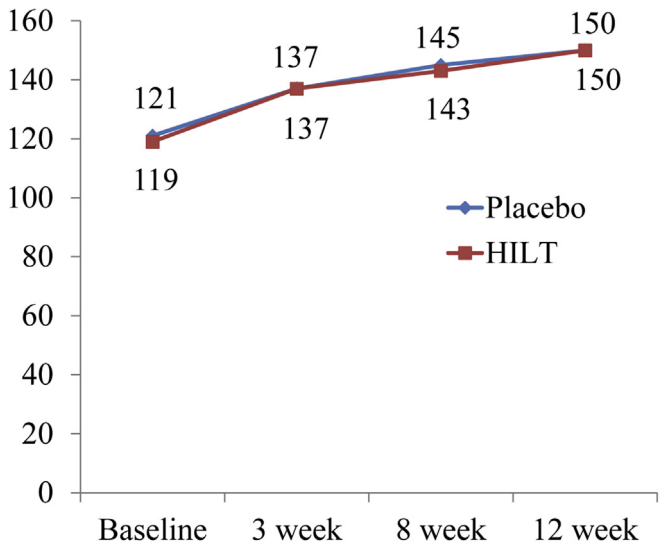

Fig. 5. Forward flexion (FF), showing the improvement over time. No statistically significant difference was observed between the two groups at serial follow-ups. HILT: high-intensity laser therapy.

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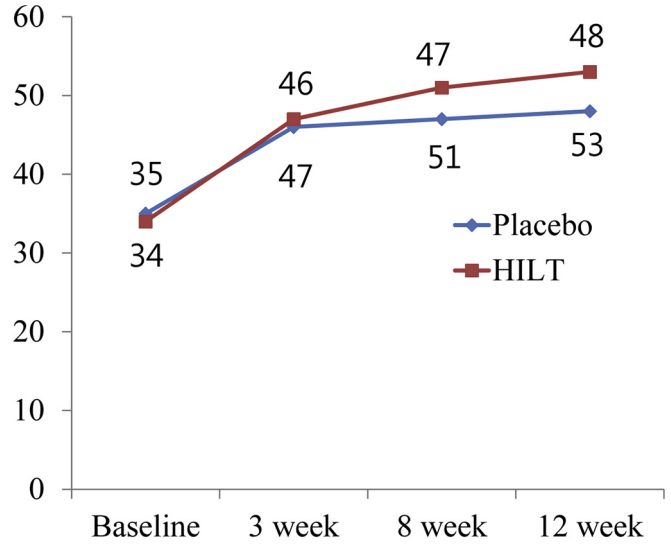

Fig. 6. External rotation at side (ER), showing the improvement over time. No statistically significant difference was observed between the two groups at serial follow-ups. HILT: high-intensity laser therapy.

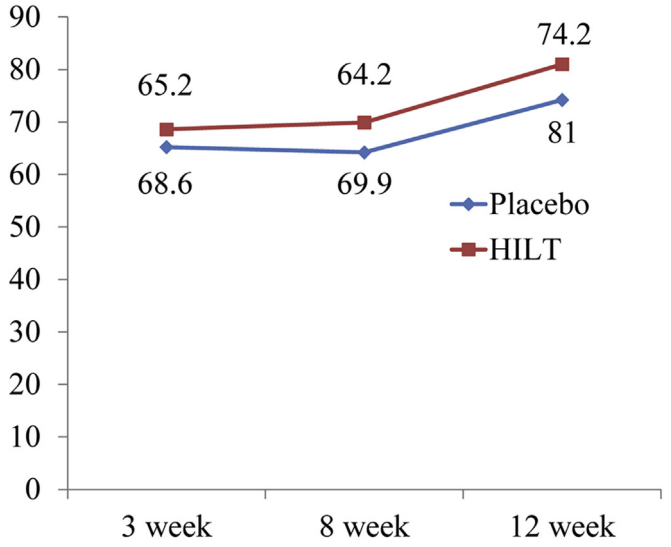

Fig. 8. VAS for satisfaction, showing no difference between the two treatments. HILT: high-intensity laser therapy.

Whatever the mechanism of action of laser therapy, its clinical benefits occur both when it is used as monotherapy (Ceccherelli et al., 1989; Chow et al., 2006) and when it is used in conjunction with a regular exercise and stretching regimen in orthopedic disorders (Hakguder et al., 2003; Gur et al., 2004). In clinical settings, a combination of laser therapy and a home-based exercise regimen is probably preferable and more cost-effective.

Recent clinical results of HILT are promising with various musculoskeletal disorders (Santamato et al., 2009; Fiore et al., 2011; Stiglic-Rogoznica et al., 2011; Alayat et al., 2014; Dundar et al., in press; Kheshie et al., 2014). In one study, HILT was compared with low-intensity laser therapy for osteoarthritis of the knee (Kheshie et al., 2014). Better pain reduction and functional results were observed for the HILT group than the low-intensity laser therapy group. Thus far, one study has evaluated the efficacy of HILT in a shoulder disorder, comparing HILT with ultrasound therapy for subacromial impingement syndrome (Santamato et al., 2009). After 2 weeks, pain was significantly decreased in the HILT group compared to that of the ultrasound therapy group. After 10 treatment sessions, the authors observed statistically significant inter-group differences in motion, functional scores, and muscle strength. Another study comparing the effect of HILT and ultrasound therapy for low back pain reported better outcomes for HILT over ultrasound therapy (Fiore et al., 2011).

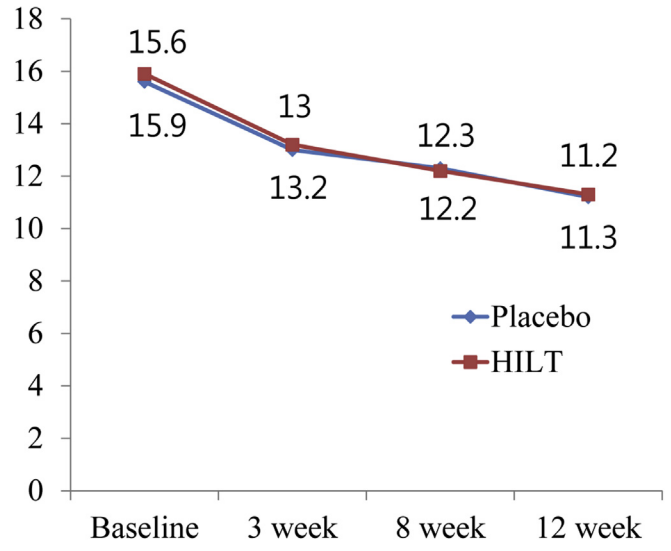

Fig. 7. Internal rotation at back (IR), showing the improvement over time. No statistically significant difference was observed between the two groups at serial follow-ups. Note that the vertebral level was numbered serially as follows: 1–12 for 1st–12th thoracic vertebra, 13–17 for 1st–5th lumbar vertebra, and 18 for any level below the sacral region. HILT: high-intensity laser therapy.

Some factors must be considered when using laser therapy. First, HILT should be avoided in cases of photoallergy. Second, there are still no guidelines on the dose, duration, and frequency of HILT in specific disorders and previous studies set these values at their own option (Santamato et al., 2009; Štiglić-Rogoznica et al., 2011; Alayat et al., 2014; Dundar et al., in press; Kheshie et al., 2014). However, there have also been no guidelines for low-intensity laser therapy, which was used prior to HILT (Chow et al., 2009). Nevertheless, previous studies have reported a dose–response relationship in low-intensity laser therapy (Bjordal et al., 2001, 2008; Chow et al., 2009). According to one study, the energy delivered in low-intensity laser therapy is not harmful, with no serious side effects observed, irrespective of the amount of energy delivered (Dundar et al., 2007).

This study has several limitations. First, it was relatively short. A long-term study may be helpful in evaluating the final consequences of HILT. However, HILT was applied only during the first 3 weeks. Therefore, it is assumed that no difference can be observed after 12 weeks, which was the time point at which the result showed no difference in both groups. As noted in other studies, 3 months of follow-up may be adequate for comparison of short-term treatment effects (Ryans et al., 2005; Leung and Cheing, 2008; Santamato et al., 2009; Favejee et al., 2011). Second, this study did not include other adjuvant treatments for comparison. This study was designed primarily to verify the effectiveness of HILT in frozen shoulder. A further comparative study is needed in order to confirm whether HILT is more effective than other adjuvant therapies in management of frozen shoulder. Third, there are no definitive “gold standard” diagnostic criteria for diagnosis of the disorder. Our inclusion for ROM is somewhat subjective and special imaging, ultrasonography or MRI, was not performed for each

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patient in this study. Reviews of the diagnostic criteria used in clinical trials of frozen shoulder have found that all researchers reported that restricted movement must be present, however, the amount of restriction was inconsistently defined (Green et al., 1998; Yang et al., 2007; Oh et al., 2008; Schellingerhout et al., 2008; Kim et al., 2014; Russell et al., 2014; Page et al., 2014b). It is possible that cases with intra-articular pathologies or rotator cuff disorders could have been included. However, the diagnosis of frozen shoulder was traditionally based on clinical impression after ruling out other pathologies via a physical examination and radiographs (Lewis, 2015; Struyf and Meeus, 2014). Since this was a randomized control trial, all conditions should have been the same in both groups. Finally, in both groups, the use of NSAIDs and the self-exercise program could have affected the results. However, in the clinical setting, pain control, together with medication and self-stretching exercise, is a common procedure in patients with frozen shoulder. Thus, in keeping with previous studies, we believe that the inclusion of these treatments was appropriate for verifying effectiveness of an adjuvant therapy.

In summary, HILT was effective in reducing pain in frozen shoulder after 9 sessions of treatment for 3 weeks and at early follow-up (8 weeks). However, the recovery of the ROM and patient satisfaction did not differ between the HILT group and the placebo control. The treatment can be considered useful in management of pain, which is the main concern of patients in the early treatment period. Given the lack of difference in pain relief at the final follow-up, further study is needed in order to verify the adequate dose, frequency, and duration of the treatment.

5. Conclusion

Patients with frozen shoulder had significant pain relief following treatment with HILT for 3 weeks and at short-term follow-up (8 weeks). However, no difference was observed at the final follow-up (12 weeks). HILT is a noninvasive adjuvant treatment, which can be used to minimize pain associated with frozen shoulder during a self-exercise regimen.

Acknowledgments

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