Bal A, Eksioglu E, Gurcay E, and et al. Low-Level Laser Therapy in Subacromial Impingement Syndrome. Photomedicine and Laser Surgery 2009; 27(1):31–36.

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Design: Randomized clinical trial

Objective: To assess whether laser therapy improves the outcome of a comprehensive home exercise program in the treatment of patients with subacromial impingement syndrome (SIS).

Population /sample size/setting:

- 40 volunteer patients (20 males, 20 females) who were newly diagnosed SIS patients admitted to a research hospital in Turkey.
- Eligibility criteria included diagnosis of SIS, aged 18-70, presence of shoulder pain, positive Neer and Hawkins-Kennedy signs, and a positive subacromial injection test.
- Exclusion criteria included other shoulder pathology, acute trauma, osteoarthritis, calcification, malignancy, prior treatment in the last 6 months, contraindications for injections, or previous shoulder surgery.
- All participants answered questions about their demographics and medical history, and underwent a detailed physical exam of the shoulder. Shoulder x-rays were taken to exclude other conditions.

Interventions:

- Forty-four patients were randomized into one of two groups by selecting a sealed, unmarked envelope containing their written treatment group. The 2 groups were laser with home exercise (n=22, mean age = 52), and home exercise alone (n=22, mean age = 53). Two patients in each group were lost to follow-up.
- Participants in both groups were given the same 12 week comprehensive home exercise program. Exercises began with pendulum circumduction and passive shoulder self-stretching. Exercise progressed to Theraband exercises with three different resistances and strengthening exercises for the muscles of scapular stabilization. It then advanced to muscle strengthening exercises with dumbbells. All the patients were invited to the clinic twice weekly to ensure compliance and to be instructed regarding the new exercise. Hot pack application before and cold pack application after shoulder exercises were recommended.
- In addition to the exercise program, the laser group received Ga-As laser therapy that was applied 5 times per week for 2 weeks in 10-minute sessions. The laser was applied over the greater and lesser tuberosities, the anterior and posterior faces of the capsule, and the subacromial regions. Each point was treated for 2 minutes. The head of the instrument was held perpendicular to the body surface and in skin contact without pressure. A Ga-As diode laser instrument (Roland Serie, Elettronica Pagani, Paderno, Italy, Mod IR 27/1) was used (wavelength 904 nm, 5500 Hz frequency, 27 Watts maximum power output per pulse, 13.2 mWatts average power, 0.8-cm^2 spot size, 1.6 J of total energy was delivered per point at each session at a power density of 16.5 mWatts/cm^2, and the cumulative energy per point for all sessions was 16 J).

Main outcome measures:

- Outcome variables included night pain measured using the visual analog scale (VAS). The Shoulder, Pain, and Disability Index (SPADI) was administered to all patients to evaluate shoulder disability and pain. SPADI total, SPADI pain, and SPADI disability forms were all used. The University of California–Los Angeles end-result score (UCLA), which is scored on a 35-point scale, was used to assess the effectiveness of treatment at the second and 12^{th} weeks. The UCLA evaluated pain, function, and range of motion. SPADI and VAS measurements were taken before treatments at baseline, and again at 2 and 12 weeks post-treatment.
- There was no statistically significant difference between groups with respect to age and gender or other demographic variables.
- There were no statistically significant differences between the 2 groups at baseline in the median VAS scores for night pain, or median SPADI scores.
- Both groups showed a significant reduction in night pain and SPADI scores at the second and 12th weeks of follow-up compared to baseline values, with the exception of the SPADI-total score at the second week in the laser group which showed a smaller non-significant reduction.
- There were no significant differences between groups in mean actual changes in night pain and SPADI scores at the second week compared to baseline or for SPADI scores at the 12^{th} week compared to baseline. However, there were significant differences between groups in mean actual changes in night pain at the 12^{th} week compared to baseline with a larger reduction in pain observed in the laser group (54.7 vs 31.5).
- UCLA results improved significantly in both groups at the 12th week in comparison with the second week. Second and 12th-week UCLA scores did not differ between the two groups.

Authors' conclusions:

- A significant improvement compared to baseline was achieved in both groups regarding pain and disability, but only night pain was significantly different between the groups after 12 weeks of treatment with the laser group displaying a larger mean actual change.
- This study demonstrated that the combination of laser therapy and a home exercise program was nearly as effective as the home exercise program alone in the treatment of SIS. Exercise alone is an effective treatment option for SIS, while laser therapy had no additional advantage.
- This study was unable to demonstrate a distinct beneficial effect of laser energy over exercise alone in the treatment of SIS. This may be related to failure in selecting the correct laser dose, duration, or application.
- Laser together with the standard exercise regimen and the standard exercise regimen alone as interventions could not be found superior to each other in the treatment of subacromial impingement syndrome.
- A comprehensive home exercise program should be the primary therapeutic option for the rehabilitation of SIS.
- Future studies that assess the effectiveness of different laser wavelengths and dosages in larger patient groups with shoulder disorders are needed.

Comments:

- The major limitations of this study were the small number of patients in each group and the absence of a sham treatment group.
- Another limitation of this study was that the energy dose per point applied was 20% less than World Association of Laser Therapy dosage recommendations for supraspinatus and infraspinatus tendinopathies. This may have influenced the results of this study.
- Medians and mean changes were reported for the outcome measurements, making it difficult to fully assess the differences. Actual means and standard deviations for all time points would have been preferred.
- There were significant differences noted between groups in mean actual changes in night pain at the 12^{th} week compared to baseline with a larger reduction in pain observed in the laser group. The greater reduction in the mean in the laser group is collectively due to both regression of the mean and treatment effects and it is impossible to tease this out without knowing the actual baseline and 12-week means. However, it is doubtful that there is any significant difference between the groups in night pain means at the 12^{th} week (not reported), since the 12 week median for night pain was the same for both groups (15.0).
- The participants did know which treatment group they were in and were informed about the nature of the study and the study protocol.
- It is unclear which outcome is the primary outcome measure.
- Adherence to the home exercise program and any differences between the groups was not reported. The authors failed to report if there were any differences in attendance at the twice weekly physical therapy sessions between the groups as well.
- The same physician, who was blinded to the participant's treatment group, assessed all patients at baseline and at the 2^{nd} and 12^{th} weeks.
- All patients were instructed on the exercises. It is not clear if the instructors were blinded to the treatment groups, or performed the laser treatments. Unblinded instructors may have conducted their instructions for exercise or applied laser treatments differently between the groups.
- This study included only 20 participants in each intervention group. The relatively small number of patients in each group resulted in an underpowered study which was not sensitive enough to detect a difference in total SPADI scores between intervention groups. For the actual mean changes of the SPADI scores, the group differences between treatment groups was small compared to the large standard deviations of the mean changes of the 2 groups. A real difference in the means between the 2 groups for the SPADI scores cannot be excluded. The small sample size resulted in great uncertainty in the estimate of the effect.
- Limiting the laser treatment to 2 weeks may have impacted the ability of the study to achieve the maximal therapeutic benefit of laser for many patients and thereby reduced the ability of the study to show an effect for this intervention. This would underestimate the effect of the intervention.

Assessment*:*

Although satisfactory in methodology and execution for the most part, this study is inadequate for evidence for or against low level laser in the treatment of patients with

subacromial impingement syndrome, because the study was underpowered (due to a small sample size) to detect any real effects. This study does not support use of low level laser for treatment of patients with subacromial impingement syndrome.