Yeldan I, Cetin E, and Ozdincler AR. The effectiveness of low-level laser therapy on shoulder function in subacromial impingement syndrome. Disability and Rehabilitation 2009; 31(11):935–940.

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Design: Randomized clinical trial

Objective: To evaluate the effectiveness of low level laser therapy in addition to an exercise program on shoulder function compared to placebo laser therapy in the treatment of patients with subacromial impingement syndrome (SAIS).

Population /sample size/setting:

- 60 patients (13 males, 47 females) who were diagnosed with subacromial impingement syndrome by their referring physician and were recruited by the Department of Physical Therapy and Rehabilitation at the University of Istanbul in Turkey.
- Eligibility criteria included diagnosis of SAIS by demonstrating at least three of the following: (1) a positive Neer test, (2) a positive Hawkin's test, (3) pain with active shoulder elevation, and (4) pain with isometric resisted abduction.
- Exclusion criteria included rotator cuff tears, presence of acute trauma, acromioclavicular arthritis, frozen shoulder, neurologic or inflammatory diseases, referring pain due to neck pathologies, history of physical therapy within the past 6 months, and subacromial or intraarticular injection within the past 3 months.

Interventions:

- Sixty-seven patients were randomized into one of two groups using the Microsoft Excel randomization function. Sixty patients completed the 3-week program. The 2 groups were laser group (n=34, mean age = 55.3), and placebo laser group (n=26, mean age = 55.0).
- The study was explained to all participants that met the criteria, but they were not informed about the true nature of laser application.
- The laser group received low level laser therapy for 3 weeks for about 8 minutes during each session. The laser therapy consisted of three pulses (3 J) to each of a maximum of five tender points. Treatment was concentrated in the subacromial and anterior shoulder regions. Laser was applied for 90 seconds at each location at each session with a frequency of 2000 Hz using a GaAs diode laser instrument (Roland Serie Elettronica Pagani, wavelength 904 nm, frequency range of 5–7000 Hz and maximum peak power of 27, 50 or 2764 W).
- The placebo laser group received placebo laser therapy applied in the same way, but the device was turned off during treatment.
- Participants in both groups were given the same exercise therapy program which was carried out for 3 weeks, twice daily under supervision in the clinic and at home. The progressive exercise program included range of motion, stretching and strengthening, empty can exercises, and progressive resistance exercises with the Theraband. Each session was 15 to 30 minutes long and was supervised by the same physical therapist. After exercise, a cold pack was applied for 15 minutes.

- To promote compliance with the exercises, patients were asked to write a diary of the exercise program which was reviewed weekly.
- The single assessor was blinded to the patient's treatment group.
- One physical therapist administered all exercise therapy and laser treatments for all patients and was not blinded to the patient's treatment group.

Main outcome measures:

- Outcome variables included 1) pain measured using the visual analog scale (VAS) for pain on activity, at rest and at night; 2) function using Constant-Morley; 3) disability using the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH); 4) functional status limitation using the Shoulder Disability Questionnaire (SDQ); 5) muscle strength using a dynamometer measuring 5 forces; and 6) range of motion (ROM) for flexion, abduction, external and internal rotation, and extension.
- Participants were assessed before and after a 3-week laser and exercise program.
- Outcome variables were measured by a blinded assessor unaware of the treatment group. Patients were also blinded to their treatment group.
- Seven patients in the original placebo laser group dropped out of the study due to surgery, scheduling or personal circumstances.
- There were no statistically significant differences at baseline between the 2 groups with respect to age and gender or other demographic variables, VAS scores, symptom duration, ROM, disability, shoulder function, and muscle strength.
- After treatment, there were statistically significant improvements from baseline in VAS pain, ROM, DASH, Constant, and SDQ scores in both groups. There was no significant improvement in muscle strength measures after treatment in both groups.
- In comparison between the two groups, there were no significant differences between the groups in post-treatment VAS scores, ROM measurements, muscle strength, DASH, Constant, and SDQ scores.

Authors' conclusions:

- After 3 weeks of exercise with laser or exercise with placebo laser, both groups showed similar improvements in outcome measurements of pain, ROM, shoulder function and disability, and there were no significant differences between the two groups after the treatment.
- The results of this study demonstrate that the addition of low level laser therapy to exercise therapy was not more effective than placebo laser therapy and exercise in the reduction of pain and the improvement of ROM, disability, and functional status after 3 weeks of treatment in patients with subacromial impingement syndrome.
- There is no fundamental difference between laser and placebo laser when they are supplementing an exercise program for rehabilitation of patients with shoulder impingement syndrome.
- Although significant improvements in pain severity, ROM measurements and shoulder function and disability were observed after treatment in both groups, there were no significant differences in muscle strength after the treatment in both the groups. This result may be due to the measurement method of muscle strength. All measurements were

done in the pain-free range. However, exercise intensity and therapy duration may not have been sufficient to increase the muscle strength in this study.
- In this study, the location of laser application was on painful points. Perhaps focusing therapy on anatomical sites could produce better results.
- If the study had investigated the effects of laser using a longer therapy duration, the results may have fallen significantly in favor of the laser therapy group.

Comments:

- One limitation of this study was the small sample size.
- It is unclear which of the many outcomes, is the primary outcome measure.
- The authors failed to report if there were any differences in attendance at the exercise and laser therapy sessions between the groups or if there were any differences in compliance with the home exercise program between the groups.
- One limitation of the study was the lack of any long-term follow-up after treatment that included outcome assessments beyond the 3 week follow-up.
- Although the treating physical therapist was blind to the assessments, the treating physical therapist was not blind to group allocation and the nature of this intervention. Therefore, treatment bias may be possible and may have affected the internal validity of the study.
- This study was methodologically satisfactory as there were no major threats to the internal validity of the study.
- Limiting the laser treatment to 3 weeks may have impacted the ability of the study to achieve the maximal therapeutic benefit of laser for many patients and may have underestimated the effect of the laser intervention.
- Both groups showed significant improvements compared to baseline in pain severity, ROM measurements and shoulder function and disability after treatment. Improvements in both groups may be due to the additional cold pack application and exercise program.
- Another limitation of the study is that the intention to treat analysis was not employed.
- The authors did not include any information on sample size calculations. It is unknown if the sample size of this study was adequate to show any statistical differences between the 2 groups. However, with the current sample size, a one standard deviation difference would be detected.
- Most of the ROM improvements seen at post-treatment in both groups were statistically significant, but the increases were small and would be considered clinically unimportant. It appears the authors overestimated the statistical importance of the small differences detected and that these differences do not demonstrate a significant clinical improvement.
- Four other similar studies were statistically pooled for pain and ROM with this current study. Three were placebo-controlled low level laser studies, and one used ultrasound as the control group. See the Abrisham (2011) critique to review this data. Overall, the pooled data from these 5 studies showed an underwhelming effect of laser on pain and on active external rotation that is less than the clinically important differences for VAS pain scores and range of motion. The pooled effect sizes appear to be small and clinically unimportant.
- The biological plausibility of low level laser therapy in the treatment of subacromial impingement syndrome is very weak at best and should be questioned. Esnouf (2007) discusses the depth of penetration in human skin of the wavelengths used in low level

laser therapy. If low level laser therapy does not even penetrate the skin, is there any real biological mechanism of action for this type of treatment to work?

Assessment*:*

This study is adequate for some evidence that low level laser plus cold packs and exercise is not more clinically effective than placebo laser therapy plus cold packs and exercise in the reduction of pain and the improvement of ROM, functional status, and disability after 3 weeks of treatment in patients with subacromial impingement syndrome. The pooled effect from the 5 studies is adequate for good evidence that a clinically important effect of laser on pain and range of motion is unlikely.

References*:*

Esnouf A, Wright PA, et al. Depth of penetration of an 850nm wavelength low level laser in human skin. Acupunct Electrother Res 2007; 32:81-86.