Dogan SK, Ay S, and Evcik D. The effectiveness of low laser therapy in subacromial impingement syndrome: a randomized placebo controlled double-blind prospective study. Clinics 2010; 65(10):1019-1022.

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Design: Randomized clinical trial

Objective: To evaluate the effectiveness of low level laser therapy on pain, range of motion (ROM), and disability compared to placebo laser therapy in the treatment of patients with subacromial impingement syndrome (SAIS).

Population /sample size/setting:

- 52 patients (19 males, 33 females) who were diagnosed with subacromial impingement syndrome in Turkey.
- Eligibility criteria included diagnosis of SAIS by physical and neurological exam and magnetic resonance imaging (MRI).
- Exclusion criteria included rotator cuff tears, presence of acute trauma, acromioclavicular arthritis, glenohumeral arthritis, neurologic or inflammatory diseases, referring pain due to neck pathologies and history of physical therapy, surgery, subacromial or intraarticular injection within the past 6 months.
- All participants answered questions about their demographics and medical history, and underwent a physical and neurological exam of the shoulder, and MRI. Blood analyses included a complete blood count, biochemical markers, erythrocyte sedimentation rate and C-reactive protein.

Interventions:

- Fifty-two patients were randomized into one of two groups by selecting a sealed, unmarked envelope containing their written treatment group. The 2 groups were laser group (n=30, mean age = 53.7), and placebo laser group (n=22, mean age = 53.45).
- The placebo laser group consisted of patients who were sex- and age-matched to the patients in the laser group.
- The laser group received low level laser therapy, cold pack therapy for 10 minutes, and an exercise program carried out 5 times a week, once a day for 14 sessions. The laser therapy consisted of 5 joule/cm^2 at each of 5-6 painful points for 1 minute. The Gallium-Aluminum-Arsenide (GaAlAs, infrared laser) diode laser device (Chattanooga group, USA) with a wavelength of 850nm, power output of 100mV, continuous wave and 0.07cm^2 spot area laser was used for the laser therapy. The laser was applied with a dosage of 5 joules/cm^2 (total 15-20 joules) at a maximum of 5-6 painful points for 1 minute at each point over the subacromial region of the shoulder.
- The placebo laser group received cold pack therapy for 10 minutes, placebo laser therapy, and the same exercise program carried out 5 times a week, once a day for 14 sessions. Placebo laser was 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 5 times a week, once a day for 14 sessions. The exercise program included

range of motion, stretching and progressive resistance exercises. Each exercise was performed once a day with 10-15 repetitions.
- The physiotherapist 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 pain measured using the visual analog scale (VAS), shoulder range of motion (ROM) and function using the Shoulder Pain and Disability Index (SPADI). ROM measurements included flexion, extension, abduction, adduction, and internal and external rotation. Pain severity, ROM measurements and functional status were evaluated before treatments at baseline, and again at the end of treatment.
- Outcome variables were measured by two blinded physicians unaware of the treatment group. Patients were also blinded to their treatment group.
- All 52 participants completed the treatment.
- There were no statistically significant differences at baseline between the 2 groups with respect to age and gender or other demographic variables, VAS scores, ROM, and SPADI scores.
- After treatment, there were statistically significant improvements from baseline in pain severity, all 3 SPADI scores, and almost all shoulder ROM measurements in both groups. Improvements were noted for internal and external rotation in the laser group, but they were not statistically significant. External rotation in the placebo laser group did not improve after treatment.
- In comparison between the two groups, there were no significant differences between the groups in post-treatment VAS scores, ROM measurements, or SPADI scores. The laser group showed a somewhat larger reduction in the VAS scores, but the placebo laser group showed more improvement in SPADI scores.

Authors' conclusions:

- This study failed to demonstrate that low level laser therapy was more effective than placebo laser therapy in the reduction of pain and the improvement of ROM and functional status after 3 weeks of treatment in patients with subacromial impingement syndrome.
- Both groups showed significant improvements compared to baseline in pain severity, ROM measurements and shoulder function after treatment. Improvements in both groups may be due to the additional cold pack application and exercise program.
- Further studies with larger samples and longer follow-up are needed to demonstrate the effectiveness of laser treatment and establish optimum doses, type, frequency and duration of laser treatments.

Comments:

- One limitation of this study was the small sample size.
- It is unclear which outcome is the primary outcome measure.
- It is unclear how the participants in this study were recruited.

- The authors failed to report if there were any differences in attendance at the 14 exercise and laser therapy sessions 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.
- This study was methodologically satisfactory as there were no major threats to the internal validity of the study.
- Limiting the laser treatment to 14 sessions 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.
- 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. The nonsignificant difference between the groups observed in the SPADI scores favors the placebo laser group. If a larger difference were detected, it most likely would lean towards favoring the placebo laser group.
- 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.

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 and functional status 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.