

Abrisham SMJ, Kermani-Alghoraishi M, Ghahramani R, and et al. Additive effects of low-level laser therapy with exercise on subacromial syndrome: a randomised, double-blind, controlled trial. Clinical Rheumatology 2011; 30:1341-1346.

Critique author: Linda Metzger 4-30-14

Design: Randomized clinical trial

Objective: To assess whether the additive effects of laser therapy with exercise improves the outcome of exercise therapy alone in the treatment of shoulder pain in patients with subacromial syndrome (rotator cuff and biceps tendinitis).

Population /sample size/setting:

- 80 patients (30 males, 50 females) who were diagnosed with subacromial syndrome and presented to a clinic in Iran.
- Eligibility criteria included diagnosis of rotator cuff tendonitis or biceps tendinitis, age 18 years or older, positive Neer, Hawkins-Kennedy, and Jobe tests for rotator cuff tendinitis, and positive Speed test for biceps tendinitis.
- Exclusion criteria included other shoulder pathology, acute trauma, systemic inflammatory conditions, osteoarthritis, neurological or structural abnormality of the shoulder, pain from shoulder surgery, pregnancy, breastfeeding, anticoagulation therapy, diabetes, chest pain, cigarette smoking, and shoulder infection.
- All participants answered questions about their demographics and medical history, and underwent a physical exam of the shoulder.

Interventions:

- Eighty 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 exercise therapy (n=40, mean age = 52), and placebo laser with exercise therapy (n=40, mean age = 51).
- Participants in both groups were given the same 2 week 10 session comprehensive clinic based and home exercise therapy program. Shoulder exercise programs included strengthening, stretching and mobilization exercises in the clinic and at home. The clinic exercises were pulley and shoulder wheel exercises in all 10 sessions. Thereafter, the exercises were taught in the clinic and continued at home and included pendulum exercises, isometric shoulder exercises and active assisted exercise for shoulder muscle strengthening (deltoid, biceps, triceps, and scapula fixator muscles).
- In each of the 10 treatment sessions after the exercise therapy, the laser group received infrared laser radiation (wavelength, 890 nm in pulsed mode on 3 points on the shoulder, including anterior (coracoid), posterior (glenohumeral joint) and lateral (rotator cuff tendon) and were irradiated for 2 minutes (a total of 6 minutes) by using a laser device (Mustang-024, Russia). Also, the biceps tendon was irradiated for patients with biceps tendinitis. The energy density was 2–4 J/cm² in each of 3 points, and the cumulative energy per point for all sessions was 20-40 J). Cumulative energy for the shoulder for all sessions was 60-120 J.

- Patients in the placebo laser group were treated with placebo laser therapy. The same device which seemed to be working was used, but no laser beams were transferred to the treated area.
- One physiotherapist administered all exercise therapy and laser treatments for all patients.

Main outcome measures:

- Outcome variables included pain measured using the visual analog scale (VAS) and shoulder range of motion (ROM) in active and passive movements of flexion, abduction, and external rotation. VAS and ROM measurements were taken before treatments at baseline, and again at 2 weeks at the end of treatment.
- Shoulder ROM was measured by a blinded physician unaware of the treatment group.
- All 80 participants completed the treatment.
- There was no statistically significant difference between the 2 groups with respect to age and gender or other demographic variables.
- After treatment, there were statistically significant improvements in pain severity and all shoulder ROM measurements in both groups.
- In comparison between the two groups, there was a significant difference between groups in mean actual changes in VAS scores which showed a larger pain reduction in the laser group compared to the placebo laser group (4.4 vs 2.9).
- In comparison between the two groups, there was a significant difference between groups in mean actual changes in all active and passive ROM movements with the laser group showing statistically significant larger improvements in all ROM movements compared to the placebo laser group.

Authors' conclusions:

- A significant improvement compared to baseline was achieved in both groups regarding pain and ROM after 2 weeks of treatment.
- This study showed that laser plus exercise therapy was more effective than exercise therapy alone in the reduction of pain and the improvement of active and passive ROM in patients with subacromial syndrome (rotator cuff and biceps tendinitis).
- The results of this trial indicated that pain severity was significantly reduced and active and passive shoulder movements in flexion, abduction and external rotation were significantly improved in patients that were treated with laser and exercise therapy in comparison to exercise alone.
- Further studies with larger samples, longer term findings, and possible comparisons with other conservative interventions are needed to establish the effectiveness of this laser and exercise therapy protocol.

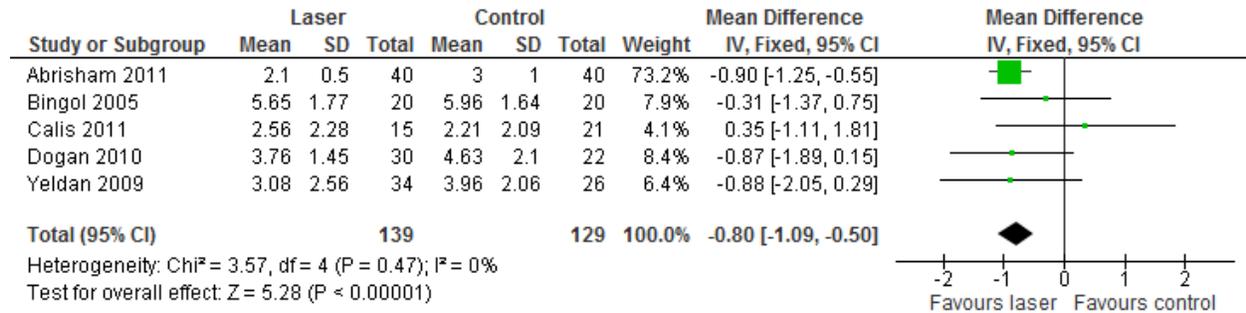
Comments:

- The major strengths of this study were the large number of patients in each group and the presence of a sham treatment group.
- Another advantage of this study was that the cumulative energy dose per point applied was in the recommended dosage range established by the World Association of Laser for

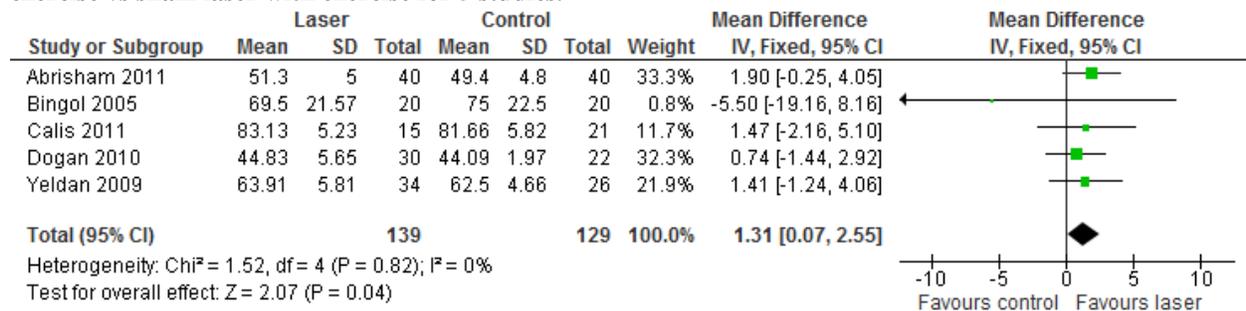
supraspinatus and infraspinatus tendinopathies. This may have influenced the results of this study.

- The authors did not report if there were any significant differences between the 2 groups at baseline in the mean VAS scores for pain, or any of the ROM scores.
- It is unclear which outcome is the primary outcome measure.
- Outcome measures were limited to VAS and ROM, and it would have been useful to have another outcome variable measuring shoulder disability.
- 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 10 exercise and laser therapy sessions between the groups as well.
- One limitation of the study was the lack of any long-term follow-up after treatment beyond the 2 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 2 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.
- If the underlying mechanism of action of laser is heat, it would be worthwhile to conduct a RCT with one intervention using low level laser and the other using superficial heat packs, and compare the differences in effectiveness of these interventions.
- The mean differences for pain VAS scores (0.9) and all ROM tests (1.9⁰ for active external rotation) between the 2 groups at post-treatment were statistically significant, but the effect sizes in favor of the laser group were small and 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 (forest plots below) for pain and ROM with this current study. Three were placebo-controlled low level laser studies, and one used ultrasound as the control group. The pooled effect sizes for laser with exercise versus sham laser with exercise was -0.80 for VAS pain and 1.31⁰ for active external rotation in favor of laser for the 5 included studies. These pooled effect sizes are smaller than the clinically important differences of 1.5 points for VAS pain scores and at least 5⁰ for range of motion. The spans of the confidence intervals include only clinically insignificant effect sizes as well. Overall, the pooled data from 5 studies shows 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.
- It is unclear why the standard deviations for VAS pain scores in this current study are smaller than the other 4 studies.

Forest plot showing pooled effect of laser with exercise vs sham laser with exercise for VAS pain scores for 5 studies.



Forest plot using random effects model for active external rotation showing pooled effect of laser with exercise vs sham laser with exercise for 5 studies.



Assessment:

This study is adequate for some evidence that laser plus exercise therapy is minimally more effective than exercise therapy alone in the reduction of pain, but has no effect on range of motion, in patients with subacromial syndrome (rotator cuff and biceps tendinitis) after 2 weeks of treatment. 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:

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