

**Stergioulas A. Low-Power Laser Treatment in Patients with Frozen Shoulder: Preliminary Results. Photomedicine and Laser Surgery 2008;26:99-105.**

Design: Randomized clinical trial

Study question: Does an 8 week course of low-level laser treatment (LLLT) improve shoulder pain, disability, and range of motion more effectively than placebo in patients with frozen shoulder?

Population/sample size/setting:

- 63 patients (40 men, 23 women, mean age 56) who completed a clinical trial of LLLT for frozen shoulder in a university-affiliated rehabilitation management and physical therapy in Greece
- Eligibility criteria were a diagnosis of frozen shoulder based on limited motion of the glenohumeral joint with pain at the extremes of the available range of motion, with more restriction in lateral rotation ( $<8^{\circ}$ ) relative to abduction and medial rotation, and no clear signs of shoulder pain caused by another condition such as rotator cuff pathology
- Exclusion criteria were insulin-dependent diabetes, bilateral symptoms, inflammatory joint disease, treatment with steroid injection or physical therapy in the past 6 months, conditions such as uncontrolled hypertension or peptic ulcer for which steroids are contraindicated, calcification of the shoulder joint, previous surgery, dislocation, or fracture of the joint, pregnancy, or a complete rotator cuff tear

Main outcome measures:

- The original study cohort had 74 patients who were randomized to LLLT (n=37) or placebo (n=37); 11 dropped out after 6 treatments to seek other treatment because of a lack of improvement of symptoms (6 in the experimental group and 5 in the placebo group), leaving 63 patients: 31 LLLT and 32 placebo
- Both groups attended 12 sessions of treatment over a period of 8 weeks: 2 sessions per week for 4 weeks followed by 1 session per week for 4 weeks
  - o Both groups were instructed in pendulum and pain-free shoulder exercises to do at home
- LLLT consisted of application of a laser device of 810 nm wavelength, continuous diode, energy density  $3.6 \text{ J/cm}^2$ , total dose per session 14.4 J, applied to 8 points in the shoulder region with the most pain identified by the patient
- Placebo was identical in appearance to the active laser and was checked by an independent party, such that the treating physiotherapists and patients were unaware of treatment assignment
- Outcomes were assessed at 4 weeks and 8 weeks by a physiotherapist who was blinded to treatment assignment, with a followup evaluation at 16 weeks

- Outcomes were overall pain, night pain, activity-related pain, and shoulder function as measured by several commonly used scales (SPADI, DASH, and the Croft shoulder disability questionnaire, which has 22 questions relating to difficulties in activities of daily living), and a health-assessment questionnaire (HAQ) which is an arthritis-specific functional assessment measure concerning items in eight areas of daily life
- At 4, 8, and 16 weeks, LLLT was more effective than placebo in reducing overall pain, night pain, and activity pain
  - o For example, mean activity pain at 4 weeks was 45.57 for LLLT and 67.75 for placebo; activity pain at 16 weeks was 22.54 for LLLT and 39.78 for placebo
- Similarly, LLLT was more effective than placebo at 4, 8, and 16 weeks for the disability measures (SPADI, Croft score, and HAQ); the DASH score was better for LLLT than placebo at 8 and 16 weeks
  - o Results are displayed in bar graphs with p values only, and not in numerical form as for pain scores
- Range of motion did not differ between groups at any followup time, and both groups had some improvement
  - o As with the disability outcomes, ROM is presented with bar graphs and not with numerical data

#### Authors' conclusions:

- Compared to placebo laser, LLLT improved scores on pain and disability but not on ROM
  - o This supports the hypothesis that LLLT has analgesic effects which facilitate therapeutic exercise and shoulder activity
- LLLT does not appear to affect the underlying capsular pathology, adhesion, and collagen biology in the setting of frozen shoulder

#### Comments:

- Some sources of bias appear to have been satisfactorily controlled, with adequate randomization and blinding
- However, there were 74 patients in the enrollment cohort, of which 11 dropped out after six treatment sessions
  - o This means that they dropped out just before the four week followup and were likely to be treatment failures
  - o Even though the dropouts were equally distributed between groups, the 4 week and later followup scores represent only “responders” to LLLT and placebo, and a similar proportion of treatment failures could be expected in clinical practice

- The therapeutic effects of LLLT are therefore likely to be inflated over what is likely to occur in everyday practice
- However, the effect of LLLT would not necessarily be eliminated if complete followup data had been present for the entire study cohort
- The HAQ measure was one of the functional outcomes, but is not described as such in the reference given by the authors for that questionnaire (Paul 2004); this is not a major flaw, since the SPADI and DASH are likely to capture salient effects of shoulder function, and the Croft questionnaire (Croft 1994) also covers relevant activities involving shoulder function
- Presentation of data only with bar graphs and p values for function and ROM obscures somewhat the effect measures dependent on numerical data
- As is often the case in studies of adhesive capsulitis, the phase of the natural history of that condition is not clear; if the randomization is effective, there is expected to be an equal distribution of early, middle, and late (resolving) phases of the condition between the two treatment groups

Assessment: Adequate for some evidence that 12 sessions of LLLT at a wavelength of 810 nm and a dose per session of 14.4 J, delivered at 8 separate points in a painful shoulder, is more effective than a placebo in reducing pain and improving function in the setting of frozen shoulder

#### References:

Croft P, Pope D, et al. Measurement of shoulder related disability: results of a validation study. *Ann Rheum Dis* 1994; 53: 525-528.

Paul A, Lewis M, et al. A comparison of four shoulder-specific questionnaires in primary care. *Ann Rheum Dis* 2004;63:1293-1299.