**Tascioglu F, Degirmenci NA, Ozkan S, and et al. Low-level laser in the treatment of carpal tunnel syndrome: clinical, electrophysiological, and ultrasonographical evaluation. Rheumatol Int. 2012; 32:409–415.**

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**Design:** Randomized, prospective, placebo-controlled, double-blinded trial

**Objective:** To investigate the effectiveness of low-level laser therapy (LLLT) in treating patients with carpal tunnel syndrome (CTS).

**Population /sample size/setting:**

* A total of 60 patients including 46 females and 14 men (mean age 48 years) with clinical and electrophysiological evidence of CTS were recruited at the Department of Physical Therapy and Rehabilitation in a university hospital in Eskisehir, Turkey. Only dominant hands of the 9 patients who have bilateral CTS were included in the study.
* The 60 patients were randomly assigned to one of the 3 treatment groups: group 1 (n = 20) received regular dose LLLT; group 2 (n = 20) received a small (half) dose LLLT, and group 3 (n = 20) received placebo LLLT.
* Inclusion criteria included symptom duration of less than 6 months.
* Exclusion criteria included history of wrist surgery, fracture, carpal tunnel injection, evidence of conditions that mimic CTS or interfere with its evaluation, such as proximal median neuropathy, cervical radiculopathy, polyneuropathy, brachial plexopathy, or thoracic outlet syndrome, history of underlying disorders associated with CTS such as diabetes mellitus, rheumatoid arthritis, pregnancy, acromegaly, hypothyroidism or renal disorders, patients with anatomical variation of the median nerve in the carpal tunnel area, history of physical therapy, and uncooperative patients.

**Methods/Interventions/Outcome Measures:**

* Study design was a prospective, randomized, placebo-controlled, double-blind study.
* Patients included in the study were randomly assigned to one of three groups using a secure system of opaque closed envelopes that were numbered from 1 to 3. The physician who assigned the patients was blinded to the treatment they would receive. Each group consisted of 20 patients.
* The patients were not informed of their treatment assignments. Patients were not allowed to use any NSAIDs or braces prior and throughout the study.
* All LLLT and placebo treatments were applied once a day, 5 days a week for a total of 3 weeks equaling 15 treatments. All patients were treated by the same physiotherapist who was not blind to the treatment groups.
* For all groups, a Gal-Al-As diode laser device (Endolaser 476, Enraf–Nonius, Netherlands) was used. A total of 5 points across the median nerve trace were irradiated with the laser probe. The diameter of the laser beam at treatment point was 1 mm. For groups 1 and 2, the laser was set to deliver a continuous form of energy with a power output of 50 mWatts and a wavelength of 830 nm.
* Patients in group 1 received laser irradiation at each of 5 points on the skin overlying the median nerve on the volar side of the wrist. A 2 minute irradiation of 1.2 joules at each point (a total of 10 minutes) was given at each treatment session. The total dose per treatment was 6 joules, and the accumulated dose for 15 treatments was 90 joules.
* Patients in group 2 received laser irradiation at each of 5 points on the skin overlying the median nerve on the volar side of the wrist. A 1 minute irradiation of 0.6 joules at each point (a total of 5 minutes) was given at each treatment session. The total dose per treatment was 3 joules, and the accumulated dose for 15 treatments was 45 joules.
* The patients in group 3 were treated with placebo laser. The 5 points were irradiated for 2 minutes each (a total of 10 minutes) with 0 joules. For the placebo laser treatment, the laser device appeared to be working, but no laser beams were actually transferring.
* A blinded physician unaware of the treatment allocation performed the clinical assessments at baseline (pre-treatment) and at the end of the therapy at 3 weeks. The 4 clinical outcome measures were change from baseline in symptom severity and functional status using the self-assessment Boston questionnaire (BCTQ) Symptom Severity and Functional Status Scales, change from baseline in pain severity using the Visual Analogue Scale scores, and changes in grip strength using a hydraulic hand dynamometer.
* In addition, median nerve conduction tests using 4 parameters were performed by a neurophysiologist who was blinded to the clinical and ultrasonographic findings of the subjects. Tests were performed at baseline and again at post-treatment.
* Ultrasonographic examinations were performed by a trained radiologist blinded to the physical and electrophysiological findings of the subjects. This test is helpful in evaluating CTS and measures the maximum cross-sectional area of the median nerve to assess nerve thickening. Tests were performed at baseline and again at post-treatment.
* A one-way ANOVA using the baseline scores as covariates was used to compare the differences in all outcome measures between groups. The significance level of the study was set at *p* < 0.05.

**Results:**

* No significant differences were observed between the groups for the demographic characteristics. Average duration of symptoms in the 3 groups was 4.67 months. All 60 selected participants completed the study.
* Baseline measurements before any treatments for all of the outcome measures were not significantly different between the 3 groups.
* There were statistically significant improvements within all 3 groups for all of the clinical outcome measures from baseline to the end of treatment at 3 weeks. Pain scores decreased significantly in all groups at the end of the study, and significant improvements were observed in grip strength, and symptom severity and functional status scores in all groups at the end of the study. However, there were no statistically significant differences between the groups for VAS scores, grip strength, symptom severity and functional status scores.
* Only one of the 4 nerve conduction parameters showed a statistically significant improvement from baseline to the end of treatment at 3 weeks. There were no statistically significant differences between the groups for any of the nerve conduction tests at the end of the 3 week treatment.
* The cross-sectional area of median nerve as measured with ultrasonography did not show any significant improvement within the groups at the end of the treatment. In comparing the changes in cross-sectional area of the median nerve between the groups, no significant difference was observed.
* There were no significant differences between the groups for any of the outcome measurements at the end of the treatment.
* No systemic or local side effects were reported during or after the treatment period.

**Authors’ conclusions:**

* The results of this study showed that LLLT given at two different dosages is no more effective in reducing pain, and improving CTS symptoms, grip strength, function, electroneuromyographic, and ultrasonographic parameters than is placebo.
* This study could not demonstrate any superiority of LLLT over placebo. All 3 groups showed similar clinical results.
* There were no statistically significant differences in any of the outcome measures between the three groups at the end of the study. The study found no significant difference relative to the cross-sectional area of the median nerve among the groups at the end of the treatment.
* The exact therapeutic mechanisms of laser therapy are not completely understood. Different experimental studies suggest that low-power laser therapy has anti-inflammatory and analgesic effects. LLLT may have the potential to induce biophysical effects within the nerve tissue.
* There is no consensus in the literature regarding the optimally effective therapeutic dose and treatment schedule for laser therapy. The minimal effective dosage is in most cases unknown. In addition, different lasers may have different effectiveness in different diagnoses and parameters, such as wavelength, duration of treatment, frequency, energy density, number of treatments, and mode of delivery. It is possible that another LLLT regimen may be effective.
* One important limitation in this study was the relatively small sample size.
* Only the short-term effectiveness of LLLT was evaluated. Well-designed larger, studies with long-term follow-up are needed to determine the optimal therapeutic parameters and long-term effectiveness of LLLT.

**Comments:**

* This study supports the conclusion that LLLT is no more effective than placebo LLLT in the conservative treatment of patients affected by CTS. No statistically significant differences between the 3 groups were observed for any of the outcome measures at the end of the 3 week treatment, including the electrophysiological and ultrasonographic parameters.
* All 3 groups revealed similar improvements after 3 weeks of treatment. The significant reduction in subjective pain perception and symptom severity, and an increased function and grip strength at the end of the treatment in all 3 groups may be attributable to a “placebo effect”. A possible explanation for these non-specific treatment effects may be attributed to the attention, interest, and concern displayed by the physician or physiotherapist, or patient expectations of the treatment effects.
* Strengths of this study included outcomes assessor and patient blinding, the inclusion of a placebo control group, and independent observations. Adjusting for any imbalances in the baseline scores in the analysis by including the baseline scores as covariates in the one-way analysis of variance was another strength of the study. This analysis increases our confidence in the internal validity of the study.
* The authors failed to perform sample size power calculations for the study. It is unknown if the sample size was adequate to detect significant differences in the outcomes. Since the results were so similar for all 3 groups, it is unlikely that a larger sample size would have detected significant differences in the outcomes of the 3 groups.
* The main limitations of this study were the relatively small number of patients and lack of data describing a long-term follow-up of the patients. The primary outcome should have been clearly designated, but was not so important in this study, since none of the outcomes showed any differences between groups after treatment.
* Since the providers that administered the LLLT treatments to the participants could not be blinded to group allocation, this could introduce performance bias. It is unknown if the physicians conducting the nerve conduction tests and the ultrasonographic exams were blinded to subject allocation.

**Assessment*:***

This adequate study provides some evidence that LLLT is no more effective than placebo LLLT in reducing pain and symptoms and improving functionality in the conservative treatment of patients affected by carpal tunnel syndrome (CTS).