**Yagci I, Elmas O, Akcan E, and et al. Comparison of splinting and splinting plus low-level laser therapy in idiopathic carpal tunnel syndrome. Clin Rheumatol 2009; 28:1059–1065.**

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**Design:** Randomized, prospective, controlled, partially blinded trial

**Objective:** To compare the short-term effectiveness of low-level laser therapy (LLLT) plus splinting to splinting alone in treating patients with mild or moderate idiopathic carpal tunnel syndrome (CTS).

**Population /sample size/setting:**

* A total of 45 female patients (mean age 50.5 years) with symptoms and signs of suspected CTS were recruited at the Physical Medicine and Rehabilitation Outpatient Clinic and Electrodiagnosis Laboratory of a university hospital in Turkey. Only patients with unilateral CTS were included in the study.
* The 45 patients were randomly assigned to one of 2 treatment groups: group 1 (n = 24) received only splints to wear and group 2 (n = 21) received splints to wear and LLLT.
* Inclusion criteria included symptom duration of over 3 months, unilateral CTS, mild or moderate idiopathic CTS, and confirmed diagnosis of CTS with nerve conduction studies (NCS).
* Exclusion criteria included cervical radiculopathy, fibromyalgia, diabetes mellitus, malignancy, distal radius fracture, pregnancy, inflammatory rheumatic diseases, thyroid and renal disorders, prior CTS treatment before admission, and clinical or electrophysiological bilateral CTS.

**Methods/Interventions/Outcome Measures:**

* Study design was a prospective, randomized, controlled, partially blinded study.
* Patients included in the study were randomly assigned to one of 2 groups using randomly enumerated closed envelopes that contained one of the two treatment methods. The physician who assigned the patients was blinded to the treatment they would receive.
* The physician who conducted the nerve conduction studies and the physician who collected the clinical and demographic outcome data and assessed the Boston Questionnaire (BQ) and the grip strengths were both blinded to the treatment groups. The physician who performed the LLLT treatments and who also regularly checked for proper patient use of the splints through phone calls to both groups was not blinded to patient treatment groups.
* The patients were not blinded to their treatment assignments. There were no sham LLLT treatments.
* The LLLT plus splinting group received ten sessions of laser therapy. The splinting group was given only splints to wear. The patients were evaluated at baseline and after 3 months of the treatment.
* The primary outcome measures were 6 NCS parameters, (BCTQ) Symptom Severity and Functional Status scores, and grip strength. The secondary outcome measure was treatment response criteria. 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 months.
* Both groups were given standard cotton–polyester splints to wear in the neutral position. They were encouraged to wear the splints during nighttime and also daytime whenever possible for 3 months. The patients were checked weekly through phone calls for proper use of splints by an unblinded physician. The nerve conduction studies were performed with a Medtronic-Keypoint (Denmark, 2007) device by the same physician who was blinded to the treatment groups. Assessment of grip strength was evaluated with a Jamar dynamometer (Sammons Preston, Canada) by a physician who was also blinded to the treatment groups. The mean score of three measurements was used in statistical analysis.
* For the LLLT group only, an infrared Ga–Al–As diode laser device (Uni-laser, Asah Medico, Denmark) with a wavelength of 830 nm and power output of 30 mWatts was used. The laser probe (1 cm diameter) was applied directly and perpendicularly on points where the median nerve localized superficially for 90 seconds on each of 3 points (total 270 seconds). This was considered an irradiation dose. The dose over the wrist area was 8.1 J, and the accumulated dose for 10 treatments was 81 J. The LLLT treatments were performed by a physician who was not blinded to the treatment groups.
* For the secondary outcome measure of treatment response criteria, each patient’s treatment responses after 3 months of treatment were classified into 3 groups; full recovery, partial recovery, and no change or worsening.
* Sample size calculations were conducted and the minimum subject number necessary to detect a difference at the 5% level (α=0.05) with an 80% chance was 14 in each group.
* The difference in outcome measures between baseline and post-treatment scores for each subject was computed by Mann–Whitney and Wilcoxon tests. The significance level of the study was set at *p* < 0.05.

**Results:**

* Initially 50 patients met the inclusion criteria for the study. Four patients who did not use the splint properly and one patient who could not be reached for follow-up were dropped out leaving a total of 45 patients (45 hands) who completed the study.
* No significant differences were observed between the groups for the demographic characteristics of age, symptom duration, and body mass index. Average duration of symptoms in the 2 groups was 13 months.
* Baseline measurements before any treatments for all of the outcome measures were not significantly different between the 2 groups except for symptom severity score. The symptom severity score of the LLLT group was statistically lower than the splinting group (*p*=0.03).
* There were no statistically significant differences between the groups for any of the outcome measures at 3 months post-treatment.
* For within group differences at the 3-month follow-up, there were statistically significant improvements in 3 of the 6 nerve conduction tests in the LLLT group, but not in the splinting group. Both groups showed statistically significant improvements in symptom severity scores at 3 months. There was a significant decrease in grip strength (*p*=0.016) in the splinting group at 3 months.
* The patients were categorized according to treatment response classification criteria for the secondary outcome measure. The complete recovery rate was greater in the LLLT group but did not reach statistical significance.

**Authors’ conclusions:**

* Both the LLLT group and the splinting group provided improvements in clinical parameters, but the LLLT group was electrophysiologically superior to splinting. LLLT is an effective conservative treatment method for the majority of patients with idiopathic mild to moderate CTS. Some patients do not respond to LLLT.
* At the 3 month follow-up, the results of our study showed that the LLLT group had some significant improvements in the electrophysiological parameters and symptom severity score while the splinting group showed only improvement in symptom severity score. Both groups showed some symptomatic healing. The results for these outcomes did not show any statistically significant differences between the groups after the treatment.
* The grip strength of the splinting group decreased significantly after wearing the splint for 3 months. This demonstrated that the immobilization produced by the splinting provided symptomatic healing at the expense of muscle weakness. This negative influence of splinting on grip strength might be hiding the positive effect of LLLT in the study.
* According to the clinical response criteria (secondary outcome measure), in the LLLT group, five (23.8%) patients had full and 12 patients (57.1%) had partial recovery. Four (19%) patients had no change or worsened. In the splinting group, one patient (4.2%) had full recovery and 17 (70.8%) had partial recovery. Six (25%) patients had no change or worsened. The number of fully recovered patients is clearly higher in the laser group. None of these results reached statistical significance.
* One limitation in the study was that the sample size calculation was performed based on the primary outcome measurements, not for the clinical response criteria (secondary outcome measure). The sample size was large enough for NCS, BCTQ, and grip strength, but may be too small to detect differences in the clinical response criteria between groups.
* Future controlled trials are needed that focus on optimum dose regimens, schedules, and cost effectiveness and clarify which patients will likely respond to LLLT.

**Comments:**

* This study supports the conclusion that LLLT and splinting are no more effective than splinting alone in improving CTS symptoms, grip strength, function, and electrophysiological parameters in the conservative treatment of patients affected by CTS. No statistically significant differences between the 2 groups were observed for any of the outcome measures at the end of the 3 month treatment, including the electrophysiological and clinical parameters.
* This study could not demonstrate any superiority of LLLT and splinting over splinting alone. Both groups showed similar clinical and electrophysiological results.
* Both groups showed statistically significant improvements in symptom severity scores at 3 months. The significant reduction in subjective symptom severity at the end of the treatment in both 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 patient expectations of the treatment effects.
* Strengths of this study included outcomes assessor blinding, the inclusion of a control group, and independent observations.
* Baseline measurements were significantly different between the 2 groups for symptom severity score. Failing to adjust for this imbalance in these baseline scores in the analysis was a weakness of the study. Not performing this adjustment in the analysis decreases our confidence in the internal validity of the study.
* Since the physician that administered the LLLT treatments and who also regularly checked for proper patient use of the splints through phone calls to both groups could not be blinded to group allocation, this could introduce performance bias.
* The main limitations of this study were the relatively small number of patients and lack of a clear designation of one primary outcome, but this was not so important in this study, since none of the outcomes showed any significant differences between groups after treatment.

**Assessment*:***

This adequate study provides some evidence that low-level laser therapy (LLLT) plus splinting is no more effective than splinting alone in reducing CTS symptoms and improving functionality in the conservative treatment of patients affected by carpal tunnel syndrome (CTS).