**Pratelli E, Pintucci M, Cultrera P, and et al. Conservative treatment of carpal tunnel syndrome: Comparison between laser therapy and fascial manipulation. Journal of Bodywork & Movement Therapies 2015; 19: 113-118.**

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**Design:** Randomized controlled trial

**Objective:** To compare the effectiveness of fascial manipulation (FM), a manual therapy technique, to low level laser therapy (LLLT) in reducing pain and improving functionality in patients with carpal tunnel syndrome (CTS).

**Population /sample size/setting:**

* A total of 42 participants (29 females, 13 males, mean age 54.2 years) with CTS were recruited consecutively in the out-patient office of the Physical Medicine and Rehabilitation Department at the Recovery and Rehabilitation Agency at the University Hospital Company Careggi in Florence, Italy. Among the participants were 70 symptomatic hands which included 28 bilateral patients and 14 unilateral patients. The 70 symptomatic hands were randomized into two groups: 35 hands were treated with FM (group A) and 35 with LLLT (group B).
* Study design was a randomized, outcomes assessor blinded, controlled trial. If the patient presented bilateral CTS, the investigator flipped a coin to determine whether the participant should go into the FM or the LLLT group. Only one degree of blinding was possible, since patients were aware of their group allocation due to the modality of treatment. A control or “no treatment” group was not utilized.
* Inclusion criteria included positive Phalen’s and Tinel tests and electromyographic positive EMG showing a decrease in nerve conduction within the last six months.
* Exclusion criteria included congenital coagulopathies, use of oral anticoagulant therapy, previous treatments that ended in less than 3 months, only weakness symptoms, concomitant tumors, and systemic neurological and rheumatological pathologies.

**Methods/Interventions/Outcome Measures:**

* Patients assigned to fascial manipulation received 3 sessions of FM for 45 minutes once a week for a total of 3 weeks. The technique involved deep friction over specific points selected by a clinical examination that involved specific movement and palpatory verification. The therapist used elbow and knuckles to create friction for 2 to 4 minutes on the identified points. Each point had a surface area smaller than 2 cm2. The number of points treated in each session ranged from 4 to 8 (mean 6).
* The patients treated with LLLT were subjected to five daily sessions lasting 10 minutes each applied along the course of the median nerve at the carpal level. The laser used was an infrared diode (M300 level laser) with a wavelength of 780 to 830 nm and a power between 1000 and 3000 mW.
* Patients were evaluated at 3 time points by the same blinded physician before treatment (T0), 10 days after the last treatment (T1), and 3 months after the last treatment (T2) with the Italian clinical examination version of the self-assessment Boston questionnaire (BCTQ) which assesses symptom severity and functional status, and the visual analogue scale (VAS) for mean pain or, in the case of no pain felt, intensity of paresthesia felt in the last week.

**Results:**

* Baseline outcome measurements before any treatments on the BTCQ for symptoms and function, and VAS scores were not significantly different between the FM and LLLT groups.
* The within group results showed that the FM group presented statistically significant improvement at the 2 different measurement time points, relative to baseline, on the BTCQ symptoms and function scores, and on the VAS pain score (p <0.0001). All improvements were clinically significant as well showing large effect sizes on the BCTQ scale and a reduction of 5.2 points on a 10 point VAS scale. The improvement in these scores remained at the 3 month follow-up.
* The within group results showed that the LLLT group presented statistically significant improvement at the 10 day follow-up time point, but not at the 3 month follow-up, relative to baseline, on the BTCQ symptoms and function scores and on the VAS pain score (p <0.0001). The improvements were clinically significant on the BCTQ scale showing very small effect sizes at the 10 day follow-up, but the small reduction of 0.5 points on the 10 point VAS scale was not clinically significant. The improvement in these scores did not remain at the 3 month follow-up.
* The between group results showed that at both follow-up time points, all 3 outcome measures were significantly different between the FM and LLLT groups with the FM group showing much greater improvements compared to the LLLT group (p <0.0001).
* None of the patients dropped out of the study and no adverse effects were observed in patients after the treatments.

**Authors’ conclusions:**

* This study supports the conclusion that FM is more effective than LLLT in the conservative treatment of patients affected by CTS. The group that received FM showed a significant reduction in subjective pain perception and an increased function assessed by the BCTQ at the end of the treatment and at 3 month follow-up. The group that received LLLT showed an improvement in the BCTQ at the end of the treatment, but the improvement level was not sustained at the 3month follow-up. Only the patients treated with FM showed significant improvement on the BCTQ and the VAS that was maintained at the 3 month follow-up (p < 0.001).
* FM appears to be an appropriate treatment not only for musculoskeletal dysfunction, but also for common nerve entrapments as in carpal tunnel syndrome. The method is effective and non-invasive. It gives excellent results for the relief of local symptoms and for restoring functionality with benefits that remain at three month follow-up.
* Due to treatment failure and complications of carpal tunnel releases, it is suggested that a conservative treatment of FM should be prescribed first before surgery.
* This study has limitations due to the lack of long-term follow-up assessments and post-treatment electroneuromyographic evaluation. Double blinding was impossible given the different modalities of treatments.
* Future studies should increase the number of patients, include a control group, and include a long-term follow-up assessment.

**Comments:**

* The primary outcome measurement of the study was not clearly designated. Three outcome measures were used (BCTQ symptoms, BCTQ function, and a change in VAS pain score) and measured at 2 different time points after treatment.It is unclear which outcome measure at which time point is the primary outcome.
* No data on demographic characteristics were given and so it is unknown if the groups differed significantly in demographic characteristics.
* Sample size calculations were not presented. It is unknown whether the sample size was large enough and the study adequately powered to detect significant differences in all the outcome measures. This decreases our confidence in the internal validity of the study.
* Since the providers that administered the FM and LLLT treatments to the participants could not be blinded to group allocation, this could introduce performance bias.
* Strengths of this study included outcomes assessor blinding, and reporting the raw scores and mean differences for between group differences at each follow-up time point. This greatly helps with the interpretability of the results.
* A major limitation of the study was that it violated the assumption of independent observations for the Student T test which was used for data analysis. The observations in this study lack independence from one another, since most (56) of the 70 symptomatic hands analyzed in this study came from patients with bilateral CTS. For observations to be independent, they must come from different individuals. Non-independent observations can make the results of the Student T Test incorrect or misleading, or simply give too many false positives. Because the conclusions from this study are suspect for violating the assumptions of the statistical test, the conclusions are rejected.
* Another important limitation of the study was the exclusion of a placebo control group. A placebo sham laser group could have easily been added. The addition of this group would have helped to determine if there were any real benefits for LLLT for patients with CTS.
* On Table 2, *p* values for the LLLT group for the second time point were misprinted with decimal places incorrect.
* Future studies should increase the number of patients, include a non-treatment control group, post-treatment electroneuromyographic evaluation, and include a long-term follow-up assessment.

**Assessment*:***

* This study does not support the evidence statement that fascial manipulation is more effective than low level laser therapy in the conservative treatment of patients affected by CTS, because it violated the statistical assumption of independent observations, and thus the conclusions are rejected.