
Design: Randomized Crossover Trial

Population/sample size:
- 11 CTS cases seen at PM&R clinic of Boston VA center
- All had failed to obtain relief with NSAIDS and splints for 3 to 30 months (mean 16 months); one had surgical release 12 years prior to entry
- All had 2 or more signs/sx of CTS: paresthesias in median n distribution, Phalen, Tinel, nocturnal wakening, hypoesthesia, wrist/hand pain
- Cases defined as mild if sensory latency >= to 3.6 ms with motor latency <= 4.3 ms; moderate if median latency >= 3.6 ms and motor latency >=4.3 ms
- Subjects excluded if needle EMG showed denervation with positive waves or fibrillation; these cases referred to hand surgeon

Main outcome measures:
- McGill Pain Questionnaire (MPQ) scores, nerve latencies, and Phalen/Tinel ascertained at baseline and 1 week after each of 2 treatment sessions: sham and real treatment
- Real treatment consisted of 45 minute sessions of red-beam laser, infrared laser, and microamp TENS applied to designated acupuncture points on hand and wrist, 3 times per week for 3-4 weeks
- Sham treatment had identical schedule with same devices in place; in all sessions, devices placed behind hanging black curtain with hand placed underneath and through
- Clinicians assessing outcome blinded to real/sham treatment
- 4 patients received real treatment first followed by sham; 7 patients received sham treatment first followed by real
- Placebo responders, defined as reporting more than 50% pain reduction after sham treatment, removed from MPQ analysis; 2 in sham first group and 1 in real treatment first group; 8 MPQ sets of scores analyzed by paired t-test
- Among 8 placebo non-responders, MPQ scores decreased from mean of 21.9 to 3.8 after real treatment; 7/8 had success defined as 50% reduction in pain
- Sensory latency had no change on sham rx; on real rx, significant mean decrease of -.215 ms was measured
- No change in motor latency with real or sham rx

Authors’ conclusions:
- Low-level laser and microamp TENS are useful conservative treatment for earlier stages of CTS
- Suggested pt selection criteria would be mild-moderate cases without denervation on EMG and with motor latencies <=7 ms
- Cost to treat 1 case is about $1000 for 15 office visits; supplemental home rx could be done with equipment cost of about $550
Comments:
- Good designation of pt selection criteria and inclusion of cost estimates help to formulate guideline recommendations
- As with most crossover studies, carryover of group with real rx first makes response to sham rx difficult to interpret, but this does not undermine basic results or conclusions
- Not clear whether combination of all 3 components is necessary for response, or if one component only is responsible for results obtained
- Analysis of raw data from Table 2 shows that inclusion of placebo responders still yields significant pre-post real treatment scores and no difference in pre and post sham scores
- Independent t-test of baseline pain scores for all subjects shows no difference between sham first and real first groups (authors reported this only for placebo non-responders)

Addendum 2009: Assessment is adequate for some evidence of effectiveness of laser plus TENS; again, it is not clear which component or components are effective