Medical Laser Systems, Inc.

Carpal Tunnel Syndrome Clinical Trial Summary

Study Design

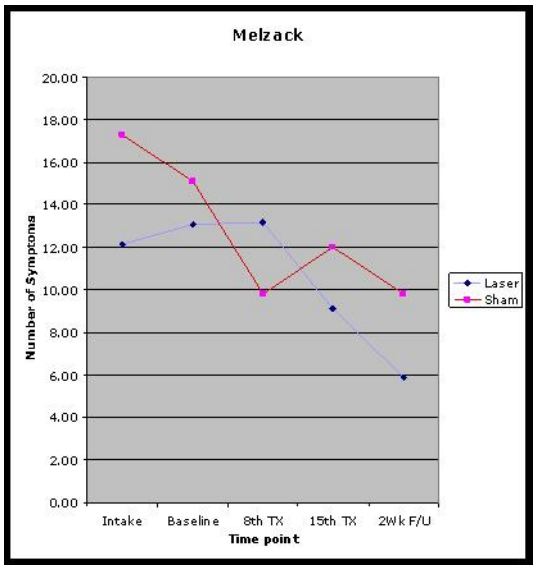
Objective: To determine whether low level laser therapy (LLLT) applied to hand, wrist, arm, shoulder and neck points by means of the Luminex Laser Therapy System significantly reduces pain and improves grip strength in patients with mild to moderate Carpal Tunnel Syndrome (CTS). A reduction of 30% in pain score, and an improvement of 25% in grip strength are deemed clinically significant.

Design: Randomized, double-blind, within subjects trial. Patients and staff administering treatment and outcome measures are blinded.

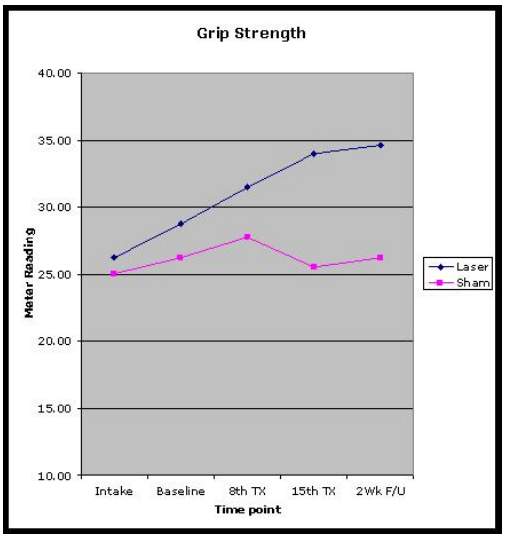
Statistical Analyses: We will compare the percent change from pretreatment level in both the active and sham treatment groups. The percent change measure should allow us to account for the variability in the intake/baseline measures that will undoubtedly be present in this relatively small sample (screening criteria should prevent floor or ceiling effects). Separate non-parametric forms of the oneway ANOVA (Friedman test) will be used to determine if significant change took place in either the sham control or active treatment groups. This should give us the maximum power for this study (directly comparing change over time within each subject).

Results and Data Analysis

Study goals have been achieved. No adverse events were reported during the study. Twenty-six patients had enrolled, with two dropping from the study prior to the mid-study evaluation measure, one due to an unrelated medical problem, and one due to a scheduling conflict. Since only intake and baseline measures had been gathered, data from these two subjects were excluded from the analyses.



Within subjects analyses indicated that the subjects receiving laser treatment experienced on average an approximate 35% reduction in their subjective feelings of discomfort by the last treatment. This feeling of relief continued to grow after treatment stopped such that at the 2 week follow up visit they were experiencing on average over a 45% reduction in their subjective feelings of discomfort. This exceeded the 30% improvement criteria for study success.



A parallel profile was seen with the less subjective measure of grip strength. By the last treatment, the subjects who had received laser treatment were experiencing on average a 20% increase in grip strength. At the 2 week follow up visit the subjects who had received laser treatment were experiencing on average a 28% increase in grip strength. This exceeded the 25% improvement criteria for study success.

Finally, subjects in the sham treatment group showed transient improvement in reported level of discomfort without any increase in grip strength.