General Motors Study

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Low Level Laser Therapy in the Treatment of Carpal Tunnel Syndrome

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ABSTRACT

This randomized double blind prospective study compares the efficacy of physical therapy (PT) combined with low level laser therapy (LLLT) in the treatment of Carpal Tunnel Syndrome against a program of physical therapy alone. Subjects on disability with diagnosed carpal tunnel syndrome were randomly assigned to the active or sham laser groups. Sensory threshold, grip and pinch strength and wrist range of motion were measured as functional tests for each subject. Other evaluations included upper extremity blood flow, median nerve EMG conduction and latencies and return to work following the treatment program.

Muscular function was improved for both the physical therapy only group and for the physical therapy plus laser group, with a significantly greater improvement for the laser group in measures of grip and pinch strength ($p < 0.05$ for grip in a wrist flexion or extension posture and for pinch grip). There was also a significantly greater improvement in range of motion in the radial deviation plane for the laser treated group. Sensory thresholds were not significantly affected by laser treatment nor was wrist blood flow. EMG conduction and latencies showed statistically significant improvement for combined physical therapy and active laser only for motor nerve conduction velocity across the wrist ($p < 0.05$). Most significantly however, the group receiving combined PT plus LLLT showed a significantly higher incidence of return to work post-treatment (72% vs 41%. $p < 0.05$). suggestive of both functional improvement and subjective improvement on self-evaluation.

These data indicate that low-level therapy, when used in conjunction with a program of physical therapy intended to mobilize and strengthen the wrist and upper quadrant, improves functional measures of wrist-hand work performance and results in greater probability of return to work than physical therapy alone. Further research is needed to address efficacy of laser

therapy alone in the treatment of CTS, to define the optimal treatment dosage and to evaluate treatment at the earliest stages of symptom development.

PURPOSE

Carpal tunnel syndrome is a major contributor to disability costs for US industry, and has a significant impact on the affected worker's overall quality of life. In addition, product quality and productivity are likely to be adversely affected through loss of skilled workers to temporary or permanent disability and from direct effects on work capabilities in less severe cases.

Present treatment for the syndrome typically consists of anti-inflammatory drugs, rehabilitation through physical therapy, and surgical release of the flexor retinaculum in the most severe cases. Each of these approaches has met with limited success in restoring function, relieving pain and returning a person to productive employment. This research project was designed to determine whether a combined program of low level laser therapy and physical rehabilitation was effective in the treatment of symptomatic carpal tunnel syndrome, and also whether the addition of low level laser therapy enhanced functional recovery compared to physical therapy alone in the treatment of carpal tunnel syndrome.

SUMMARY AND CONCLUSIONS

- Functional measures of grip strength, important to assembly jobs, were positively affected by both the physical therapy program and the combined program of physical therapy and laser irradiation.
- The improvement was significantly greater in the group which also received laser irradiation of the carpal tunnel area transcutaneously, and the fraction of subjects showing improvement was greater for the laser group.

- Sensory thresholds were not significantly improved during the 5-week treatment period for either physical therapy alone or therapy plus laser. Additional time to allow nerve regrowth, perhaps with periodic follow-up treatments, might improve sensory recovery.
- Wrist range of motion was not affected by treatment, except for radial deviation, which was significantly improved for the laser treated group.
- EMG data were inconclusive, with the only statistically significant difference in pre versus post treatment EMG's for the active laser group appearing in motor nerve latency recorded across the wrist. A statistically significant difference for the inactive laser group was noted for palmar sensory latencies.
- Wrist blood flow measured non-invasively was increased both for subjects having prior surgical release and for those not surgically treated, but the differences observed were not statistically significant. The absence of changes in major vessel blood flow through the carpal tunnel supports the hypothesis that any circulatory changes occurring post-treatment are at the microvascular level.
- Return to work was approximately 72% for the active laser group versus 41% for the placebo laser, a statistically significant treatment difference ($p < 0.05$).
- These data show that low-energy laser therapy improves functional measures of wrist-hand work performances and improves probability of return to work when used in conjunction with a program of physical therapy intended to mobilize and strengthen the wrist. Further research is needed to address efficacy of laser irradiation alone in the treatment of CTS, and to evaluate treatment at the earliest stages of symptom development.

SIGNIFICANCE

Functional measures of grip strength, important to assembly jobs, were positively affected by both the physical therapy program and the combined program of physical therapy and laser treatment. The improvement was significantly greater in the group which also received laser irradiation of the carpal tunnel area transcutaneously. These data suggest that low-energy laser therapy combined with physical therapy improves functional measures of wrist-hand work performance and increase the probability of return to work. Further research is required to address the efficacy of laser treatment alone in the treatment of CTS, especially for early stages of the syndrome.

INTRODUCTION

Carpal Tunnel Syndrome is the most common peripheral neuropathy, and occurs most frequently after 40 years of age.(5) Early reports indicated the syndrome occurs more frequently among females than males, and can be associated with a number of etiologies, typically involving repetitive motion and gripping with the hand when the wrist is in a severely flexed or extended posture. Symptoms include paresthesias and numbness in the distribution of the median nerve, muscle weakness and ultimately atrophy of the hand muscles innervated by the median nerve. A recent study evaluated the benefit of exercise on carpal tunnel symptoms, and found a general improvement in strength which produced some improvement in functional measures of grip strength but no improvement in self-assessment of hand comfort. (16)

Previous studies have documented that irradiation of central or peripheral nerve with low-energy laser light results in improved central and peripheral nerve conduction. (11-13) reduced scar tissue formation and degeneration after nerve crush injury, (1,1D,14) more rapid regeneration of injured peripheral nerve, (9,11,14) reduced tissue inflammatory responses and enhanced blood flow, (2,3,14) In addition, clinical studies are beginning to corroborate the

efficacy of laser treatment in neuromuscular injury and inflammation. (2,4,7,17) the exact interaction of the laser light with the tissue is not completely defined, though no harmful consequences have been identified in either experimental or clinical studies. (2,3,4,7,14)

The purpose of this study was to determine efficacy of a combined program of physical therapy plus low-energy laser therapy of the carpal tunnel area transcutaneously, and to compare it with physical therapy alone as non-surgical treatment of Carpal Tunnel Syndrome. This study was designed to validate preliminary clinical observations which showed functional improvement in CTS patients treated with the low power laser. The present study compared treatment outcome, including return to work, using a prospective, double blind design. Since the laser employed in the study uses a red diode light for aiming and the laser wavelength is invisible and of sufficiently low power that it produces no discernible heating, neither the patient nor physician knew whether active or sham laser treatment was being delivered.

Since temperature increase is insignificant and unlikely to explain observations, direct membrane effects and photochemical activation are the most probable explanations for observed effects. (3,6,8,11,15) Experimental measurements have been made demonstrating increased neuronal metabolism following low level laser irradiation, and evidence for direct membrane effects is seen in increased action potential amplitude after irradiation of isolated nerve. This study evaluated whether the observed physiologic interactions of low-energy infrared light with biological, specifically neural and vascular, tissue can effectively reverse the pathophysiologic changes caused by chronically elevated pressure on the median nerve within the Carpal Tunnel.

METHODS

Subjects

Employees diagnosed with carpal tunnel syndrome were eligible to participate in the study. The diagnosis of carpal tunnel syndrome was confirmed by one of the principal

investigators (WTG) based on clinical history, evaluation of the symptom complex of pain and burning or tingling paresthesias in the fingers and hand in the distribution of the medial nerve, a positive Tinel's sign (distal tingling on percussion) and Phalan test, and an abnormal baseline electromyogram (EMG). If an employee was eligible for participation, signed informed consent was obtained before his or her enrollment in the study.

A total of 119 subjects entered the program, and half were randomly assigned to receive physical therapy plus laser treatment and half received physical therapy plus "sham" laser treatment. All subjects were enrolled in the physical therapy program to receive as much benefit from conventional treatment as possible. The treatment program lasted five weeks for each subject, with pre and post treatment evaluation based on conduction latencies on the EMG. Grip strength for wrist in extended and flexed postures and pinch grip, tactile sensation threshold for light touch, carpal tunnel anatomy from magnetic resonance imaging and forearm, wrist and hand blood flow using non-invasive magnetic resonance flowmetry. The final evaluation parameter was return to work post-treatment. Participation was voluntary and all testing done as part of the study was non invasive (with the exception of the EMG, which is a normal part of the diagnostic work-up and follow-on), carrying no risks to the subjects.

Treatment and Evaluation Protocol

Once enrolled in addition to the clinical history, physical examination and EMG, baseline studies measured tactile sensitivity of the distribution of the median nerve in the hand using the Semmes Weinstein Monofilament test and motor assessment of grip and wrist strength and torque plus wrist range of motion, using the UDO workset for wrist and grip assessment and UDO active conditioning and evaluation equipment for shoulder evaluation and therapy. Also, wrist blood flow was quantified non-invasively using the Metriflow AFM-100 Blood Flow Scanner for magnetic resonance based measurement of regional blood flow

Upon completion of the baseline phase, all volunteers began a five week physical therapy program specifically designed for the treatment of carpal tunnel syndrome. Initial grip and pinch strength and range of motion tests established the beginning functional levels for each volunteer and served as the basis for design of a physical rehabilitation program. These parameters were monitored regularly throughout the program and again objectively measured at the completion of the five weeks.

At the beginning of physical therapy, half the volunteers (the experimental group) were randomly assigned to low level laser treatments and half (the control group) were assigned to receive sham laser treatments. The study was double-blinded in that neither the volunteer nor the physical therapist knew which laser system was active: those records were maintained separately until completion of the study. The laser system was only used by personnel who had successfully completed the appropriate laser certification course to minimize any risks to participants and to assure the proper protocol was followed. The low energy laser therapy is not sufficient intensity to cause measurable heating within the tissue. The MicroLight 830 Laser System (Lasermedics, Stafford, TX) operates at 830 nm wavelength to penetrate 3 to 5 cm of tissue, sufficient to penetrate the median nerve within the carpal tunnel. The three lasers comprising a single system have a mean power output of 90 mW, which are timed to deliver a 33 sec treatment cycle. Each laser was regularly calibrated by a technician not involved in patient treatment to ensure that power output was within specifications. Eye safety glasses absorbent for 830 nm were worn at all times during treatment by both the patient and the health professional, consistent with the HRC protocol as reviewed and approved by the GM Human Subjects Review Board.

Subjects continued any medications prescribed by their doctor for the course of the study, and these were noted for potential interaction and confounding effects. End points for each

subject were completion of the five weeks of physical therapy or withdrawal from the study of any reason.

At the end of the five week program, another clinical history, physical examination and evaluation of symptoms was performed. Objective measurements were also repeated for EMG, grip and pinch strength, range of motion evaluation, tactile sensation and blood flow measurements. The final end-point evaluated was return to work. Statistical evaluation of the functional motor and sensory data was performed using the Wilcox on Rank Sum Test, both to compare values before and after the treatment program and to compare the experimental group with the control group, with $p < 0.05$ indicating statistical significance. A two-tailed Student's t-test for paired observations was used to evaluate the EMG latency data for within group differences and between group differences were evaluated using the t-test for difference of the means.

RESULTS

Demographics of Subjects:

Table 1 shows the demographic characteristics of the two treatment groups. Note that although subjects were placed in the two groups on a random selection basis, the placebo laser group which received physical therapy alone had a higher proportion of females (60% vs 46%) and a somewhat higher incidence of prior hand surgery for carpal ligament release.

Functional Assessment:

Table 2 presents the data on functional changes observed following physical therapy and physical therapy plus laser irradiation. All changes are given as percent of pre-therapy baseline. In an attempt to normalize for initial differences in subjects strength. A positive number represents a functional improvement while a negative one is a worsening. The significance levels shown for Group A vs B represent incremental benefit of the laser treatment beyond

physical therapy alone, and show a significant benefit for measures of static grip strength and for wrist range of motion in the plane of radial deviation.

Table 3 breaks the data in a different manner, and presents a comparison of patients whose symptoms (and capabilities) improved during treatment versus those whose worsened. Both groups had a few subjects exhibiting no change on one or more measures, and these have been omitted from the analysis. Note that the average improvement among those showing improvement from Group B is notably larger than in Table 2, with smaller difference in the values for Group A. This is probably a result of a higher incidence of symptomatic worsening in Group B receiving physical therapy only. These negative changes would, therefore, reduce the mean benefit calculated for the group. Also note that the maximum improvement for the combined therapy group is substantially larger than the maximum improvement for the physical therapy only group (for those showing improvement).

Wrist Blood Flow Evaluation:

Table 4 shows pre and post-treatment values for wrist and blood flow for a total 132 wrists which were divided into three groups on the basis of symptoms and whether or not prior surgical release of the carpal tunnel had been performed. Although the data are consistently suggestive of improved wrist blood flow post-treatment, particularly for the group receiving treatment with the active laser, the differences do not attain statistical significance. Since it is anticipated that any circulatory changes occur at the microvascular level, this is not surprising.

TABLE 1

Demographic Characteristics of the Groups

	Group A - Active laser	Group B - Sham laser
Mean Age = sd	43.4 = 9.0	43.7 = 6.6
Male / Female	22 / 19	19 / 29
Hand Surgery	50%	63%

Table 2

Mean Percent Change in Function

Parameter	Group A Laser &Phys.Ther .	Group B Physical Ther. Only	Statistical signif. Grp.A vs Grp. B
Sensory Thresh			
Median n., extend.	1.4%	2.0%	n.s.
Median n., flexed	2.8%	2.5%	n.s.
Grip Strength			
Flexion	48%	14%	$p < 0.01$
Extension	41%	11%	$p < 0.01$
Pinch	28%	15%	$p < 0.05$
Peak Torque	17%	8%	n.s.
Wrist Torque			
Flexion - 60o/s	30%	36%	n.s.
180o/s	5%	48%	n.s.
Extension - 60o/s	12.8%	25%	n.s.
180o/s	-3.6%	10%	n.s.
Wrist Work			
Velocity = 60o/s	30.5%	48%	n.s.
Velocity = 180o/s	26.7%	20%	n.s.
Range of Motion			
Flexion	14.1%	1.3%	n.s.
Extension	11.7%	5%	n.s.
Radial Dev.	31.2%	-2.9%	$p < 0.01$
Return to Work	**72%**	**41%**	**$p<0.05$**

TABLE 3

**Comparison of functional Measures -
Improved Function versus Deteriorated Function
(Distribution and Average Change)**

	Group	%	Avg.Change	Ranges	%	Avg.Changes	Range
Flex Grip	A	87	47%	3-543%	13	11%	2-30%
	B	72	26%	3-85%	28	19%	2-55%
Ext. Grip	A	79	50%	1-334%	21	22%	4-39%
	B	68	25%	1-145%	32	16%	2-60%
Pinch Grip	A	76	52%	4-300%	24	25%	3-97%
	B	67	42%	5-200%	33	29%	7-91%
GripTorque	A	65	38%	1-225%	35	19%	4-100%
	B	68	31%	1-110%	32	16%	1-61%

TABLE 4

**Wrist Blood Flow (ml/min/100cc tissue)
Mean Values by Group, Pre- and Post-treatment**

Diagnosis	n	Laser	Pre-Treatment	Post-Treatment
Asymptomatic	56	Active	2.67	2.78
		Sham	2.72	2.73
Symptomatic	59	Active	2.63	2.72
		Sham	2.31	2.34
Symptomatic	73	Active	2.52	2.92
With prior surgery		Sham	2.76	3.06

TABLE 5

Mean Nerve Conduction Latencies
Pre- and Post-treatment
Mean Value (+/ - Std. Dev.)

Nerve/Site Tested	# of Wrists	Laser	Pre Treatment	Post-Treatment
Motor	27	Active	55.54 (3.1)	56.45 (2.9)
	27	Sham	56.28 (4.3)	56.89 (2.6)
Sensory	25	Active	55.79 (2.7)	67.15 (4.1)
	28	Sham	2.37 (.32)	58.12 (2.6)
Palmar	11	Active	2.33 (.2)	2.16 (.27)
	11	Sham	2.37 (.37)	2.15 (.21)*
Wrist motor	27	Active	4.77 (.70)	4.33 (.81)**
	37	Sham	4.54 (.67)	4.39 (.57)
Wrist Sensory	27	Active	3.97 (.56)	3.85 (.64)
	32	Sham	3.93 (.61)	3.89 (.51)

* Significant treatment effect $p < 0.05$

** Significant treatment effect $p < 0.05$

Nerve Conduction Velocities from EMG

Table 5 shows mean nerve conduction velocities for various subsets of the median nerve and various segments of the nerve. The only two significant differences of pre- versus post-treatment mean latencies are indicated as determined by the paired t-tests. None of the active versus sham laser comparisons were statistically significant.

Return to Work

Most importantly, perhaps, there was a statistically significant difference in the percentage of the two groups actively working at 90 days post-treatment. The group receiving

physical therapy plus sham laser treatment had a return to work rate of 41% while the group receiving physical therapy plus active low level laser therapy had a return to work rate of 72%, a statistically significant treatment difference. ($p<0.05$).

DISCUSSION

Consistent with a prior study, we found that physical therapy alone did result in improvement of grip strength. (18) However, in an extension of the scope of that study, we found a greater proportion of the subjects showed improvement in grip strength when the physical rehabilitation was supplemented by treatment with low-level laser therapy. Also, both the mean improvement for all subjects and the mean improvement for just those subjects who did improve (omitting those who deteriorated or stayed the same) were significantly greater for subjects receiving combined therapy which included the laser than for those receiving physical therapy alone. This strongly argues that the laser irradiation is having a beneficial effect, whether through reduction of inflammation, either pre-existing or exercise induced during the treatment period, or through facilitating restoration of function in partially damaged median nerve fibers. In addition, both groups exhibited an improvement in grip torque, wrist torque and wrist work, though the benefit was less apparent as velocity of wrist movement was increased. This is consistent with improvements in strength observed in previous studies using physical therapy to treat carpal tunnel syndrome. There was not a significant difference between the two groups in these dynamic measures of wrist function, perhaps because they reflect action of lower arm, not hand, muscle groups and voluntary contraction which is affected by hand comfort during the movement. Since sensory function was not improved in the relatively short five-week treatment period, the level of discomfort during wrist movement may not have been substantially affected.

Notably, the significant difference in functional improvement between the two treatment groups was reflected in a significant improvement in return to work, evaluated at the end of 90 days. In addition to reflecting improved function, this difference in percentage working post-therapy indicates an improved subjective evaluation on the part of the subjects, with a resultant increase in ability to work.

Further research is needed to resolve several issues. First this study used a single treatment paradigm, selected on the basis of clinical experience and prior usage of the laser for treatment of soft tissue injury. The appropriate oose-response characteristics remain to be defined for treatment of CTS. In fact the optimal dosage and treatment regimen may differ at different stages of the disease. The second for further study is to define the mechanism(s) of action. This study was not designed to address this issue or to contribute additional data for our understanding of physiologic mechanisms of laser interaction with human tissues, and does not provide any. (The blood flow data suggest some insights; those data are being prepared for publication separately.) Second, the efficacy of laser treatment by itself was not tested in the protocol, although prior anecdotal clinical evidence suggests a positive benefit for laser treatment alone. Third, all subjects participating in this study were long-standing CTS cases, many with surgical release of the carpal ligament. One might expect the efficacy of this treatment protocol to be even greater when delivered during the earliest stages of CTS, perhaps just as symptoms begin to emerge. Finally, the issue of return to work will require a more broadly based study, perhaps one without confounding influences inviolability of jobs or considerations of seniority to attain proper job placement.

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Lay Summary:

The disabling symptoms of carpal tunnel syndrome brought on by cumulative repetitive trauma can very quickly remove a person from the workforce and have a significant impact on his or her lifestyle and overall quality of life. Increasing recognition of the syndrome has brought the realization that it has spread throughout the workforce in near epidemic proportions and resulted in economic costs in the United States alone in the hundreds of millions of dollars annually.

The syndrome has become particularly prevalent in production and manufacturing workplaces (such as General Motors) which must bear the economic burden this imposes. Present treatment for the syndrome typically consists of attempted rehabilitation through physical therapy, with surgery performed to relieve the worst symptoms, but these efforts have met with very limited success in returning a person to productive employment. This research proposal was designed to evaluate the effects of an intensive physical therapy rehabilitation program specifically designed for employees with carpal tunnel syndrome and simultaneously determine the added benefit of low level laser therapy applied directly to the affected wrist(s). The low energy laser used in this study is not of sufficient intensity to cause heating within the tissue, and protective glasses were provided by the treating health professional and worn by subjects and therapists at all times the laser was activated. The exact interaction of the laser light with the tissue is not completely defined, though no harmful consequences have been identified in either experimental or clinical studies.

Of the 116 subjects enrolled in this study, half were randomly assigned to receive laser therapy; all subjects received an intensive physical therapy program designed to benefit carpal tunnel. The treatment program was conducted over a five week period and results analyzed for both subjective impression of change in symptoms and objective measurements of physical strength, tactile sensation and range of motion. Participation was voluntary and all testing was

non-invasive (with the exception of the EMG, a normal diagnostic procedure which is minimally invasive). The results demonstrate that low-energy laser irradiation given in combination with a program of physical therapy for hand/wrist rehabilitation does improve functional measures of hand and wrist work performance. The data also show that the combined therapy including laser irradiation is significantly more effective than physical therapy alone. Further research is needed to optimize treatment parameters, to evaluate the efficacy of laser treatment provided without physical therapy and to investigate the effectiveness of treatment at the earliest stages of symptom development.

In addition, significant research continues at General Motors and elsewhere to better define the causal factors in initiation of Carpal Tunnel Syndrome. As we better understand the ergonomic and biomechanical factors which are causing development of Carpal Tunnel syndrome it will become possible to effectively redesign assembly processes and products to significantly reduce the incidents of CTS.