Carpal Tunnel Syndrome Pain Treated With Low-Level Laser and Microamperes Transcutaneous Electric Nerve Stimulation: A Controlled Study

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ABSTRACT. Naeser MA, Hahn K-AK, Lieberman BE, Branco KF. Carpal tunnel syndrome pain treated with low-level laser and microamperes transcutaneous electric nerve stimulation: a controlled study. Arch Phys Med Rehabil 2002; 83:978-88.

Objective: To investigate whether real or sham low-level laser therapy (LLLT) plus microamperes transcutaneous electric nerve stimulation (TENS) applied to acupuncture points significantly reduces pain in carpal tunnel syndrome (CTS).

Design: Randomized, double-blind, placebo-control, crossover trial. Patients and staff administered outcome measures blinded.

Setting: Outpatient, university-affiliated Department of Veterans Affairs medical center.

Participants: Eleven mild to moderate CTS cases (nerve conduction study, clinical examination) who failed standard medical or surgical treatment for 3 to 30 months.

Intervention: Patients received real and sham treatment series (each for 3–4wk), in a randomized order. Real treatments used red-beam laser (continuous wave, 15mW, 632.8nm) on shallow acupuncture points on the affected hand, infrared laser (pulsed, 9.4W, 904nm) on deeper points on upper extremity and cervical paraspinal areas, and microamps TENS on the affected wrist. Devices were painless, noninvasive, and produced no sensation whether they were real or sham. The hand was treated behind a hanging black curtain without the patient knowing if devices were on (real) or off (sham).

Main Outcome Measures: McGill Pain Questionnaire (MPQ) score, sensory and motor latencies, and Phalen and Tinel signs.

Results: Significant decreases in MPQ score, median nerve sensory latency, and Phalen and Tinel signs after the real treatment series but not after the sham treatment series. Patients could perform their previous work (computer typist, handyman) and were stable for 1 to 3 years.

Conclusions: This new, conservative treatment was effective in treating CTS pain; larger studies are recommended.

Key Words: Acupuncture; Carpal tunnel syndrome; Lasers; Pain; Rehabilitation; Transcutaneous electric nerve stimulation.

CARPAL TUNNEL SYNDROME (CTS) is an entrapment neuropathy of the median nerve at the wrist caused by compression of the median nerve as it passes from the forearm to the palm beneath the transverse carpal ligament.[1] Signs and symptoms associated with CTS include paresthesias; numbness and tingling in the sensory distribution of the median nerve for thumb, index, middle, and radial side of the ring finger; Tinel sign; Phalen sign; hypoesthesia; nocturnal awakening; specific pain diagrams of the hand; and sometimes hand weakness.[2-4] Nerve conduction studies (NCSs) are the primary definitive test, although the exact millisecond latencies considered to be compatible with CTS vary across studies.[1,5-7]

The etiology of CTS is unknown; however, it occurs more commonly in workers with tasks involving repetitive hand movements (eg, computer keyboard typing, operating machinery, assembly line work). It may be the result of a concentration of workload on a few smaller groups of muscles.[3] In addition to ergonomic stressors, some systemic medical disorders (eg, diabetes mellitus, thyroid disease, rheumatoid arthritis, gout, obesity) and psychosocial factors may contribute to CTS. Between 1981 and 1991, the US Department of Labor, Bureau of Labor Statistics reported an almost 10-fold increase (from 23,000 to 223,600) in disorders "associated with repeated trauma."[8,9] In 1995, 50% of all workers with CTS missed ≥30 days of work.[10]

Current standard treatments for work-related CTS include, initially, conservative treatments and, later, if necessary, surgical release of the transverse carpal ligament. Conservative treatments include adjusting the work environment, and using wrist splints, and nonsteroidal anti-inflammatory drugs.[11] Direct injection of steroids into the carpal tunnel may provide relief for only 2 to 4 months,[12] and at 18 months, only 22% of patients may be free of symptoms.[13]

Surgical release of the transverse carpal ligament is performed in approximately 40% to 45% of CTS cases, with estimates of more than 460,000 procedures being performed each year, at a direct medical cost of more than $1.9 billion.[7] After surgery, approximately one third of patients continue to experience pain and functional loss[14]; only 40% regain normal function and 5% worsen.[15,16] Office workers return to work in a few weeks and people who work in heavier labor require 4 to 6 months of rehabilitation.

In 1993, the cost to treat 1 case of CTS without surgery in California was $5246; with surgery it was $20,925.[17] The average cost to treat 1 case of CTS nationwide was about

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$12,000.[18] There is need for a new conservative treatment for CTS, which could be applied in the early stages of the disorder to permit continued employment, to prevent disability, and to reduce the need for surgery.

A new conservative treatment was tested in the present controlled study. The treatment uses low-level laser therapy (LLLT) and microamperes transcutaneous electrical nerve stimulation (TENS) to stimulate acupuncture points. The term LLLT refers to the use of low-level lasers, which are class IIIb lasers (5–500mW, red-beam or near infrared; wavelength, 600–1000nm). When applied to the skin, these lasers produce no sensation and do not burn the skin. They have been observed to increase cellular adenosine triphosphate (ATP) levels and to reduce pain in various studies (reviewed below). In addition, the application of microamps TENS has been observed to increase cellular ATP levels and reduce pain (reviewed later). The application of LLLT (instead of acupuncture needles) to stimulate acupuncture points to treat pain has been reported in studies from China[19] and other countries[19,20] for more than 2 decades.

Uncontrolled Studies Using Acupuncture or LLLT to Treat CTS Pain

Two studies[21,22] used acupuncture needles to stimulate acupuncture points to treat CTS pain, with success rates of 88% to 97%. The Chen[21] study with 36 cases included successful treatment of 14 CTS cases who had previously failed to obtain satisfactory symptom relief after surgical release. Follow-up after 5.1 years indicated continued pain relief in 24 of 29 cases.[21]

Two other studies[23,24] used LLLT to treat CTS pain with success rates of 77% to 91%. Weintraub[24] treated 30 hands with a near infrared 830-nm, 30-mW laser (9J per point, 5 points, not acupuncture points, along the median nerve at the wrist/hand). Results showed a normalization of distal latencies for compound muscle action potential in 11 hands and a tendency to improve in 23%, reversing CTS in 77% of the cases. Wong et al[23] treated a total of 35 CTS and repetitive stress injury cases with a near infrared 830-nm, 100-mW laser (12–30J per point only at the posterior neck region, cervical 5 to thoracic 1, not at the affected wrist/hand area). In an 8-month period (10 treatments), 91.4% of the cases were successfully treated; no NCS data were provided.

In a study combining needle acupuncture, LLLT, and microamps TENS to treat CTS pain, Branco and Naeser[25] found that 33 of 36 hands had more than a 50% reduction in pain after 12 to 15 treatments. The McGill Pain Questionnaire[26] (MPQ) score was significantly reduced posttreatment ($P<.0001$). This included successful treatment of 14 hands after surgical release failed to provide satisfactory pain relief. The LLLT and microamps TENS treatment protocol used in the Branco and Naeser study was the basic protocol originally developed within this current controlled study, which was ongoing at that time.[27] Mechanisms that may underlie the effectiveness of LLLT and microamps TENS to treat pain are reviewed in the next section of this article.

Mechanisms of LLLT to Treat Pain

Over the past 2 decades, LLLT has been used to treat pain associated with conditions such as musculoskeletal injuries, arthritic conditions, and postherpetic neuralgia.[28-33] Some of the suggested mechanisms underlying therapeutic effects with LLLT have been reviewed[34-36] and include the following: (1) increased ATP production by the mitochondria[37] and increased oxygen consumption on the cellular level,[38] (2) increased serotonin[39] and increased endorphins (naloxone has been observed to block the analgesic effect of LLLT with GaA1As laser),[40] (3) anti-inflammatory effects,[41,42] and (4) improved blood circulation to the skin in some cases (eg, postherpetic neuralgia,[33] diabetes mellitus[43]). The primary effects of LLLT are considered to be photobiologic rather than photothermal.[44]

Mechanisms of Microamps TENS to Treat Pain

Microcurrent TENS is a relatively new form of TENS that is used to treat chronic pain.[45-47] Most standard TENS devices use milliamperes (mA) and the patient feels a tingling sensation from the surface electrodes. Milliamps TENS is believed to reduce pain, in part, as described by the Gate Control Theory.[48] Microamperes (μA) TENS is different in that the patient feels nothing; it is applied subthreshold. It has been observed to increase ATP concentrations and protein synthesis on the cellular level, with the greatest stimulatory effects around 500μA.[49] Currents greater than 5mA can decrease the ATP concentrations and the protein synthesis and transmembrane movement of metabolites.[49]

Both LLLT and microamps TENS are appropriate for controlled research in the treatment of pain because each device produces no sensation when applied to the skin. This study examined whether application of real or sham LLLT, plus microamps TENS to acupuncture points, significantly reduces the signs and symptoms of mild to moderate CTS. This is the first controlled research to use real and sham LLLT plus microamps TENS to treat CTS pain.

METHODS

Participants

Eleven CTS cases (11 hands from 9 men, 2 women) were included in the study (table 1). The patients ranged in age from 40 to 68 years (mean, 53.5y). All had failed to obtain satisfactory pain relief with conservative treatments, including nonsteroidal anti-inflammatory drugs and wrist splints, for a period of 3 to 30 months (mean, 16mo). One patient (case 4) had had surgical release of the transverse carpal ligament. At that time, 12 years before the present study, his CTS was associated with crutches; his more recent CTS was associated with his computer work. These 11 patients were stratified into 2 groups (borderline/mild CTS, moderate CTS) based on a combination of electrodiagnostic and clinical findings.

Electrodiagnostic testing. The NCSs were performed in the Rehabilitation Medicine Service, Department of Veterans Affairs (VA) Medical Center, Boston (KAKH), with surface stimulating and recording electrodes administered with standard methodology using a TD20 MK1 EMG/EP machine.[a] Before the NCSs were administered, hand skin temperature was measured with a Derma Therm® adhesive perfusion monitor strip[b] placed on the dorsum of the hand for at least 15 seconds. The NCSs were performed only if the skin temperature was above 30°C.

The following NCS data were obtained across the carpal tunnel: median sensory peak latency, median sensory amplitude, median motor latency, median motor amplitude, and the nerve conduction velocities. The median sensory nerve test was performed as follows: for antidromic, the stimulation site was near the proximal crease of the wrist, 12 to 14cm proximal to the ring electrodes placed around the proximal and distal interphalangeal joints of the second digit. For orthodromic, the stimulation sites were the second digit ring electrodes placed near the proximal and distal interphalangeal joints, and the recording site was over the median nerve in the anterior aspect

Table 1: Demographics for 11 Mild to Moderate CTS Cases

Case	Age/Sex	Hand Treated	Duration of Symptoms	Severity of CTS	Entry Baseline, MPQ Score	Occupation
Real treatments first						
1	63/M	R (dom)	3mo	Mild	15	Producer and editor of educational videotapes
2	46/M	L (dom)	2y	Mild	23	Handyman, including electrical wiring and cement laying
3	59/F	R (dom)	2y	Mild	23	Typist, retired hairdresser; diabetes type II; Hx of stroke approx 1y before CTS Tx
4	61/M	R (dom)	2.5y	Moderate	26	Compensation records clerk, computer work; surgery, R & L transverse carpal ligament release, (crutches) 12y prior to entry; pain returned
Sham treatments first						
5	40/M	R (dom)	3mo	Borderline/mild	24	Computer software, research and development
6	42/M	L (nondom)	1y	Mild	14	Mailman, US Postal Service
7	68/M	R (dom)	2.5y	Mild	14	Retired, electrical lineman
8	48/F	R (dom)	2y	Moderate	29	RN, computer and desk work; Hx of amyloid
9	61/M	R (dom)	3mo	Moderate	8	Plumber
10	59/M	R (dom)	1.5y	Moderate	15	House painter; smoker
11	41/M	R (dom)	5mo	Moderate	33	Computer work; diabetes type II; smoker

NOTE. The cases are rank ordered by severity of median nerve motor latency at entry baseline (table 4) within each category: cases receiving the real treatment series first or cases receiving the sham treatment series first.
Abbreviations: M, male; F, female; dom, dominant; nondom, nondominant; Hx, history; Tx, treatment; R, right; L, left; RN, registered nurse.

of the wrist 12 to 14cm proximal to the ring electrodes. The median motor nerve latency was recorded from the thenar muscles, with stimulation performed at the wrist 7 to 8cm from the recording site. The active electrode was placed halfway between the metacarpophalangeal joint of the thumb and the midpoint of the distal wrist crease. For nerve conduction data, the amplitudes of all responses were measured from baseline-to-negative peak. All NCSs were performed with the same equipment and method.

Needle electromyography was performed on the abductor pollicis brevis muscle by using a monopolar needle electrode. Denervation was defined as sustained, abnormal spontaneous activity in the form of positive waves or fibrillations ranging from 0 to 4+. No cases with evidence of denervation on electromyography were accepted into this study; they were considered to have severe CTS and were referred for further evaluation by a hand surgeon.

Clinical examination. Clinical examination of the hand included evaluation of the following: motor examination of the hand intrinsic muscles, Phalen sign (60s), Tinel sign, sensation to pin and touch threshold in the fingers, frequency of finger paresthesias, and pain distribution in the hand and fingers. Patients were also asked about nocturnal awakening caused by wrist and hand discomfort. Patients with cervical radiculopathy, double-crush syndrome, or thoracic outlet syndrome were excluded. The patients were instructed not to change their pain medications during the study. The patients were evaluated by the occupational therapist (BEL) and were advised to continue wearing their splints.

Diagnostic CTS groups: borderline/mild CTS. NCS abnormality was observed only for the sensory latency. This type of patient had a median nerve sensory peak latency that was $\geq$3.6ms; however, the median nerve motor latency was $\leq$4.3ms. They also had at least 2 other signs and symptoms of CTS: paresthesias in the median nerve distribution in the thumb, index, middle finger, and radial side of ring finger; a positive Phalen sign (60s); a positive Tinel sign; nocturnal awakening; hypoesthesia; and wrist and hand pain.

Diagnostic CTS groups: moderate CTS. NCS abnormalities were observed for both the sensory and motor distal latencies. The median nerve sensory peak latency was $\geq$3.6ms, and the median nerve motor latency was $>$4.3ms. This type of patient also had at least 2 other signs and symptoms of CTS.

The research protocol was approved by the Research Committee and the Human Studies Subcommittee at the VA Boston Healthcare System and the institutional review board of Boston University School of Medicine, and signed informed consent was obtained from all participants. All devices, including the class IIIb low-level lasers, were reviewed and approved by the radiation safety officer at the VA Boston Healthcare System.

Treatment Equipment

The research protocol used the following 3 treatment devices.

Device 1. A red-beam laser[c] (continuous wave, 15-mW, 632.8-nm, helium neon laser with a 2-mm diameter probe tip). The red-beam laser is presumed to have a shallow penetration into skin (eg, only 0.8mm direct energy).[50] The red-beam laser was applied to shallow acupuncture points located on the fingers and hand.

Device 2. An infrared laser[d] (pulsed, 180ns "on" time, 9.4W, 904nm, gallium arsenide diode laser with a 5-mm diameter probe tip). In addition to the single-diode probe, the infrared device had a second probe with a 4-diode array embedded into a 6- by 6-cm block. Each laser diode in the array had the laser properties identical to that of the single-diode probe. Because infrared laser has longer wavelengths than the red-beam laser, it is presumed to have a deeper tissue penetra-

tion (up to an inch or more).[50,51] The infrared laser was applied to deeper acupuncture points located at the elbow, shoulder, upper back, and cervical paraspinal areas.

Device 3. A microamps TENS device[e] (580μA–3.5mA), which was applied to the affected wrist.

The lasers were calibrated before use, and the laser and TENS probes were wiped with alcohol before each treatment.

Procedures

Study design. This was a randomized, double-blind, placebo-control, crossover trial. The staff administering the treatments were different from the staff administering the outcome measures; the latter were blinded to which series of treatments (real or sham) each patient was about to receive or had just received. The staff administering the treatments were not blinded. Patients were randomized to receive either a series of real treatments first or a series of sham treatments first. Patients were tested on the outcome measures within a month before entering the study (entry baseline) and within a week after the end of each treatment series (posttest 1, posttest 2). The posttest 1 scores also served as pretreatment scores for the second treatment series.

Treatment procedure. Each patient received 2 series of 9 to 12 treatments, real or sham. Each series lasted 3 to 4 weeks, and patients were treated 3 times a week (Monday, Wednesday, Friday). Each session required 35 to 45 minutes. After the first treatment series, patients were reevaluated (posttest 1) and then crossed over to the alternative treatment series followed by posttest 2. Seven patients received the sham treatment series first and 4 received the real treatment series first.

During sham laser treatments, there was no emission from either the red or infrared lasers, even though the laser probe was held on the same acupuncture points/areas for the same amount of time. Dynatronics Corporation installed a laser beam cutoff mode on the red-beam laser, which was used during the sham treatments to block emission of the laser beam. Also, the Dynatron 1620[c] had a programmable timer that emitted a sound after a fixed period. Thus, the patient heard the same sound after 66.6 seconds (1J), whether the treatment was real or sham.

The emission from the single-probe infrared laser was blocked during sham treatment by setting the laser output mode to that for the 4-diode array. Likewise, when the 4-diode array was used during sham treatment, the output mode was set to that for the single probe. The Respond Systems infrared laser emitted a short tone after 30 seconds of laser beam emission, and the same tone was heard during sham treatment.

The microamps TENS device was turned off during sham treatment.

During each treatment, the patient was seated comfortably in a chair at an adjustable table. To guarantee that the patient remained blinded as to which treatment condition was being administered, all treatments were performed on the affected upper extremity, with the patient's elbow, forearm, and hand placed underneath and through the bottom of a hanging black curtain. This prevented the patient from seeing whether the red-beam laser was on or off. The infrared laser is beyond the visible spectrum.

The treatments were administered by licensed acupuncturists. The anatomic locations of the acupuncture points listed are described in acupuncture textbooks.[52] There were 3 sequential steps to each treatment session.

Step 1. The red-beam laser was placed perpendicularly directly on the skin at the center of the distal wrist crease of the affected hand, acupuncture point PC 7 (pericardium meridian), the point closest to the median nerve at the wrist crease (7J, 225J/cm^2, 7.7min).

Step 2. The circular electrode (4-cm diameter) for the microamps TENS device was applied to the skin and centered over acupuncture point PC 7, located at the center of the wrist crease, and the grounding pad was applied to the skin and centered over acupuncture point TW 4 (triple warmer), located on the dorsum of the wrist. After these were taped into place, the device was turned on. As the power intensity was gradually increased, the patient was asked if he/she felt any stimulation or tingling at either electrode site. Immediately after the patient reported sensation, the intensity level was decreased to a subthreshold level at which the patient reported no sensation. When the MicroStim 100 TENS device is used properly, there is no sensation. During real treatment, after the subthreshold intensity had been established and set, a pulsed frequency of 292Hz was used for 2 minutes followed by a pulsed frequency of 0.3Hz for 18 minutes (as suggested by the manufacturer). The microamps TENS treatment required 20 minutes.

During sham treatment, the same procedure was followed; however, the TENS device was turned off immediately after the patient felt the initial stimulation or tingling sensation. The adjustment from 292 to 0.3Hz required moving a switch that produced an audible click. This same switch was adjusted after 2 minutes during the sham condition (even though the device had been turned off). Thus, the patient heard the same click during each treatment condition.

Step 3. While the TENS device was taped into place at the wrist for 20 minutes, the red-beam laser was applied to additional acupuncture points on the affected hand (1J, 32.3J/cm^2, 66.6s per point). This included 6 points on the fingers and 5 to 8 points on the hand and wrist. The points on the fingers included Lu 11 (lung), LI 1 (large intestine), PC 9, TW 1, Hrt 9 (heart), and SI 1 (small intestine). These points were chosen because they mark the origin and termination (Well points) for 6 acupuncture meridians that pass through the wrist. LI 1, for example, is indicated to treat numbness in the index finger, a common complaint in CTS.[52] Other points chosen for treatment on the wrist and hand (eg, Lu 9, Hrt 7, Hrt 8, PC 8, Ba-Xie points in the web-spaces between the fingers) were chosen because they are local points for treatment of hand pain.

Also during step 3, the infrared laser was applied to a minimum of 5 deeper acupuncture points on the upper extremity, the upper trapezius, and cervical paraspinal areas. Each acupuncture point was treated for a minimum of 1 minute, at each of 3 pulse settings (eg, 3500, 584, and 73 pulses per second [pps]), with energy densities ranging from 1.81J/cm^2 at the highest frequency to .04J/cm^2 at the lowest frequency.

The acupuncture points treated on the upper extremity and the upper trapezius areas varied in each case, depending on the locus and direction of radiating pain. Potential points on the upper extremity included TW 5 and 9; PC 6; and LI 10, 11, and 15. The acupuncture points on the cervical paraspinal area included Hwa To points lateral to cervical 5 to thoracic 1. Other acupuncture points included GB 20 and SI 10, 11, or other locally painful points.

The single-diode infrared laser probe was applied to the single acupuncture points, as listed earlier. In some larger areas of pain, the 4-diode array was applied. The same laser treatment parameters used with the single probe were used with the 4-diode laser array (eg, 1min at each pulse setting: 3500, 584, 73pps). The patient remained in the same seated position at the table when the upper trapezius and cervical paraspinal areas were treated.

Outcome Measures

The primary outcome measure was the pain score from the MPQ[26] where the maximum possible pain score is 78 (total

Table 2: Pain Scores

Cases	Pre	Post	ΔPost–Pre (%)
Real 1st treatment	Entry Baseline	Posttest 1	
1-Mild CTS	15	0	−15 (−100%)
2-Mild CTS	23	0	−23 (−100%)
3-Mild CTS	23*	9*	−14* (−60.8%)
4-Mod CTS	26	1	−25 (−96.2%)
Mean (n=3)	21.3	.33	−21 (−98.7%)
SD	5.69	.58	5.3 (2.3)
Real 2nd treatment		Posttest 2	
5-Borderline/Mild CTS	26	0	−26 (−100%)
6-Mild CTS	36	2	−34 (−94%)
7-Mild CTS	1*	1*	0* (0%)
8-Mod CTS	24	18	−6 (−25%)
9-Mod CTS	5	0	−5 (−100%)
10-Mod CTS	20	9	−11 (−55%)
11-Mod CTS	2*	2*	0* (0%)
Mean (n=5)	22.20	5.80	−16.40 (−74.8%)
SD	11.28	7.76	12.93 (33.58)
Pooled groups			
Mean (n=8)	21.87	3.75	−18.13 (−88.78%)
SD	9.06	6.52	10.45 (28.27)
			t=4.66
Probability			P=.0035
Sham 1st treatment	Entry Baseline	Posttest 1	
5-Borderline/Mild CTS	24	26	2 (8.3%)
6-Mild CTS	14	36	22 (157%)
7-Mild CTS	14*	1*	−13* (−92.8%)
8-Mod CTS	29	24	−5 (−17.2%)
9-Mod CTS	8	5	−3 (−37.5%)
10-Mod CTS	15	20	5 (33.3%)
11-Mod CTS	33*	2*	−31*(−93.9%)
Mean (n=5)	18.00	22.00	4.20 (28.78%)
SD	8.40	11.28	10.71 (76.46)
Sham 2nd treatment		Posttest 2	
1-Mild CTS	0	0	0 (0%)
2-Mild CTS	0	0	0 (0%)
3-Mild CTS	9*	0*	−9 (100%)
4-Mod CTS	1	1	0 (0%)
Mean (n=3)	.33	.33	0 (0%)
SD	.58	.58	0 (0%)
Pooled groups			
Mean (n=8)	11.38	14.00	2.62 (17.99%)
SD	11.14	14.17	8.38 (59.69)
			t=−.89
Probability			P=.41

Abbreviation: mod, moderate.
* Case was a placebo responder during first or second sham treatment series; data excluded from *t* test comparisons.

Pain Rating Index). This questionnaire was administered by a research assistant. The secondary outcome measures included the median nerve sensory peak latency, motor latency, Phalen sign, and Tinel sign.

Statistical Analyses

Analyses were performed by using paired and unpaired *t* tests with the MPQ score, sensory latency, and motor latency data and the McNemar test for proportions with the Phalen sign and Tinel sign data.[53] All statistical tests were 2 tailed.

RESULTS

MPQ Scores

Sham treatment. Any patient who reported a greater than 50% pain reduction after a series of sham treatments was considered to be a placebo responder and was removed from further statistical analyses of the MPQ scores. Three patients were placebo responders, including 2 of the 7 patients who received the sham treatment series first (cases 7, 11) and 1 person who received the sham treatment series second (case 3) (table 2). This overall placebo response (3/11, 27.3%) is con-

sistent with placebo response rates in which sham LLLT has been included in studies to treat pain.[30]

A comparison of MPQ scores for the remaining 8 subjects established that there was no change from pre- to postsham treatment ($t_7=-.89$, $P=.41$). Because 3 subjects who received the sham treatment series second were at floor after receiving the real treatment series (table 2), the sham effect was reexamined separately for the 5 subjects who received the sham treatment series first. The mean change for these 5 subjects was +4.2, because almost exclusively of a single patient (case 7). Paired *t* test analysis established that there was still no change postsham ($t_4=-.88$, $P=.48$, power=.75) (table 2).

Real treatment. It was necessary to know whether the 2 groups (real series first, real series second) entered the real treatment series with equivalent pain scores. Prereal, the mean pain score ± standard deviation (SD) for the real first was 21.3±5.69, and the mean pain score for the real second was 22.2±11.28 (table 2). An unpaired *t* test ($t_6=.12$, $P=.91$) established that the 2 groups had equivalent pain scores prereal. Therefore, data from the 2 groups could be pooled (n=8).

A paired *t* test was performed on pre- versus postreal pain scores for these 8 cases. There was a significant reduction in pain postreal treatment ($t=4.66$, $P=.0035$). For prereal treatment, the overall pain score was 21.87±9.06; for postreal treatment, it was only 3.75±6.52. There was a mean reduction of 18.13±10.45 points on the MPQ score or −88.78%± 28.27. This represented a 6-fold reduction in pain (table 2).

Overall, 7 of 8 cases reported greater than 50% pain reduction postreal treatment, a success rate of 87.5%. The remaining case showed a decrease in pain of 25%. Four of 8 cases (50%) reported an MPQ score of 0; and 6 of 8 cases (75%) reported a pain score of ≤2.

The mean MPQ scores for pre and post each real and sham treatment series are shown in figure 1, with placebo responders omitted.

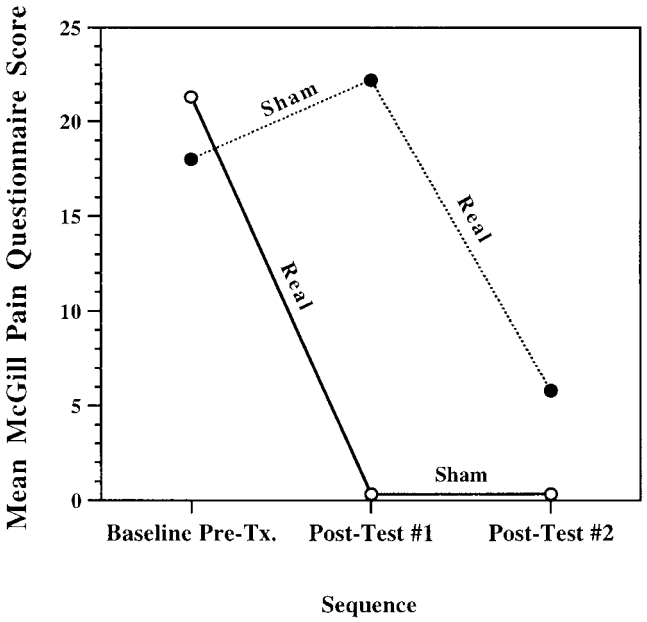

Fig 1. Mean MPQ scores for 8 CTS cases separated into 2 treatment groups (3 placebo responders have been omitted): (1) patients (n=3) who received the real treatment series first and the sham treatment second; and (2) patients (n=5) who received the sham treatment series first and the real treatment second. In the real first group, there was a 21-point decrease in pain (−98.7%) postreal, and in these cases postsham, no change. In the sham first group, there was a 2.62-point increase in pain (+17.99%) postsham, and in these cases postreal, a 16.4-point decrease in pain (−74.8%). In the pooled groups (n=8), there was a significant decrease in pain postreal (*P*=.0035) but not postsham (*P* = .41) (table 2). Legend: —○— , real treatment series first; --●--, sham treatment series first.

Sensory Latencies

Sham treatment. Pre- versus postsham data were compared for the 8 cases with complete data (table 3). The mean change was .003±.48ms ($t_7=-.02$, $P=.98$). It was felt that cases who received the sham treatment series second could have delayed effects after the real treatment series (first). For that reason, the sham effect was reanalyzed only for those subjects who received sham first. A paired *t* test for these 4 cases showed no significant change postsham ($t=-.41$, $P=.71$).

Real treatment. Cases with absent sensory latencies were excluded (cases 3, 9, 10). Prereal, the mean sensory latency for the real series first was 3.89±.38; and prereal, the mean sensory latency for the real series second was 3.95±.86. An unpaired *t* test ($t_6=-.11$, $P=.91$) established that the 2 groups had equivalent sensory latencies when entering the real treatment series. Therefore, the data from the 2 groups could be pooled.

A paired *t* test was performed on the pre- versus postreal sensory latencies for these 8 cases. There was a significant decrease in the mean sensory latency postreal treatment ($t=3.58$, $P=.009$). The mean decrease in sensory latency postreal treatment was −.215±.17ms. Seven of the 8 cases (87.5%) showed a decrease, and 1 case showed no change.

Motor Latencies

Sham treatment. Pre- versus postsham data were compared for all 11 cases. The mean change was −.209±.67ms ($t_{10}=1.04$, $P=.33$). In keeping with the previous statistical analyses, this comparison was repeated only for cases who were treated with the sham treatment series first (n=7). A paired *t* test showed no significant change in the motor latencies postsham ($t=1.49$, $P=.19$) (table 4).

Real treatment. The mean motor latency prereal for the real series first was 3.90±.53 and for the real series second, it was 4.20±1.10. An unpaired *t* test ($t_9=.46$, $P=.66$) established equivalence in motor latencies between these 2 groups.

A paired *t* test was performed on the pre- versus postreal motor latencies for these 11 cases. There was no significant change in the mean motor latency postreal treatment ($t = 1.16$, $P=.27$). The mean motor latency prereal treatment was 4.07± .910) and the mean motor latency postreal treatment was 4.20±1.10.

The Phalen Sign

Sham treatment. Pre- and postsham data were compared for the 8 cases for whom there were complete data (table 5). Because the Phalen sign is scored either as positive (present) or negative (absent), the test for change from pre- to postsham was performed by the McNemar test for proportions and using the Yates correction for continuity.[53] There was no significant change in the number of cases who had a positive Phalen sign after the sham treatment series ($z=0.5$, $P=.96$). Presham treatment, 6 of 8 cases (75%) had a positive Phalen sign; postsham, 5 of 8 cases (62.5%) had a positive Phalen sign.

Real treatment. Prereal, 9 of 11 cases (81.8%) had a positive Phalen sign, and postreal treatment, only 2 cases (18.2%) had a positive sign. The McNemar test established that there

Table 3: Median Nerve, Sensory Peak Latencies

Cases	Pre (ms)	Post (ms)	Post–Pre (ms)
Real 1st treatment	Entry Baseline	Posttest 1	
1-Mild CTS	4.32	4.00	−.32
2-Mild CTS	3.76	3.60	−.16
3-Mild CTS	Absent*	5.00*	—*
4-Mod CTS	3.6	3.60	.00
Mean (n=3)	3.89	3.73	−.16
SD	.38	.23	.16
Real 2nd treatment		Posttest 2	
5-Borderline/mild CTS	3.20	2.80	−.40
6-Mild CTS	3.92	3.84	−.08
7-Mild CTS	4.16	4.08	−.08
8-Mod CTS	3.20	3.00	−.20
9-Mod CTS	5.36*	Absent*	—*
10-Mod CTS	Absent*	Absent*	—*
11-Mod CTS	5.28	4.80	−.48
Mean (n=5)	3.95	3.70	−.25
SD	.86	.82	.18
Pooled groups			
Mean (n=8)	3.93	3.72	−.215
SD	.68	.63	.17
			t=3.58
Probability			P=.009
Sham 1st treatment	Entry Baseline	Posttest 1	
5-Borderline/mild CTS	3.20	3.20	.00*
6-Mild CTS	4.40	3.92	−.48
7-Mild CTS	4.16	4.16	.00
8-Mod CTS	No data*	3.20*	—*
9-Mod CTS	Absent*	5.36*	—*
10-Mod CTS	Absent*	Absent*	—*
11-Mod CTS	4.30	5.28	.98
Mean (n=4)	4.02	4.14	0.125
SD	.55	.86	0.61
Sham 2nd treatment		Posttest 2	
1-Mild CTS	4.00	3.92	−.08
2-Mild CTS	3.60	3.60	.00
3-Mild CTS	5.00	4.40	−.60
4-Mod CTS	3.60	3.80	.20
Mean (n=4)	4.05	3.93	−.12
SD	.66	.34	.34
Pooled groups			
Mean (n=8)	4.032	4.035	.003
SD	.56	.62	.48
			t=−.02
Probability			P=.98

* Data excluded from *t* test comparisons.

was a significant shift from pre- to postreal treatment (z=2.46, P=.014).

The Tinel Sign

Sham treatment. Pre- and postsham data were compared for the 8 cases for whom there were complete data (table 6). Only 2 patients shifted from pre- to postsham, both in the sham first group, and both cases shifted from a negative to a positive Tinel sign, indicating that the condition became worse. The McNemar test found that there was no significant change from pre- to postsham (z=1.06, P=.29).

Real treatment. All 6 patients who had a positive a Tinel sign before real treatment had a negative Tinel sign postreal treatment. None of the 5 patients who had a negative Tinel sign before real treatment developed a positive sign after real treatment (table 6). The McNemar test established that this pattern was highly significant (z=2.24, P=.025).

DISCUSSION

This is the first controlled study to apply sham LLLT and microamps TENS to acupuncture points to treat CTS. A placebo effect was observed in 3 of 11 cases (27.3%). Two placebo responders reported a greater than 90% reduction in pain after the first series of treatments that were sham (cases 7, 11). Case 11 stopped smoking cigarettes 3 days before the first sham treatment. It is not known whether this had an effect on his CTS pain. Cases 7 and 11 showed no improvement in their

Table 4: Median Nerve, Motor Latencies

Cases	Pre (ms)	Post (ms)	Post–Pre (ms)
Real 1st treatment	Entry Baseline	Posttest 1	
1-Mild CTS	3.40	3.40	.00
2-Mild CTS	3.60	3.60	.00
3-Mild CTS	4.00	4.40	.40
4-Mod CTS	4.60	4.40	−.20
Mean (n=4)	3.90	3.95	.05
SD	.53	.53	.25
Real 2nd treatment		Posttest 2	
5-Borderline/mild CTS	2.60	2.60	.00
6-Mild CTS	3.60	3.40	−.20
7-Mild CTS	3.80	3.80	.00
8-Mod CTS	3.40	3.80	.40
9-Mod CTS	5.20	5.20	.00
10-Mod CTS	5.60	6.60	1.00
11-Mod CTS	5.00	5.00	.00
Mean (n=7)	4.17	4.34	.17
SD	1.10	1.34	.41
Pooled groups			
Mean (n=11)	4.07	4.20	.13
SD	.91	1.10	.35
			t=1.16
Probability			P=.27
Sham 1st treatment	Entry Baseline	Posttest 1	
5-Borderline/mild CTS	2.20	2.60	.40
6-Mild CTS	3.80	3.60	−.20
7-Mild CTS	3.80	3.80	.00
8-Mod CTS	4.80	3.40	−1.40
9-Mod CTS	5.40	5.20	−.20
10-Mod CTS	5.60	5.60	.00
11-Mod CTS	6.50	5.00	−1.50
Mean (n=7)	4.59	4.17	−.41
SD	1.43	1.10	.74
Sham 2nd treatment		Posttest 2	
1-Mild CTS	3.40	3.60	.20
2-Mild CTS	3.60	4.00	.40
3-Mild CTS	4.40	4.00	−.40
4-Mod CTS	4.40	4.80	.40
Mean (n = 4)	3.95	4.10	.15
SD	.52	.50	.38
Pooled groups			
Mean (n=11)	4.36	4.15	−.209
SD	1.19	.90	.67
			t=1.04
Probability			P=.33

Table 5: Phalen Sign

Cases	Pre	Post
Real 1st treatment	Entry Baseline	*Posttest* 1
1-Mild CTS	+	−
2-Mild CTS	+	−
3-Mild CTS	+	+
4-Mod CTS	+	+
No. positive tests	4/4	2/4
Real 2nd treatment		Posttest 2
5-Borderline/mild CTS	−	−
6-Mild CTS	+	−
7-Mild CTS	+	−
8-Mod CTS	+	−
9-Mod CTS	+	−
10-Mod CTS	−	−
11-Mod CTS	+	−
No. positive tests	5/7	0/7
Pooled groups		
No. positive tests	9/11	2/11
McNemar test		z=2.46
		P=.014
Sham 1st treatment	Entry Baseline	Posttest 1
5-Mild CTS	+	−
6-Mild CTS	+	+
7-Mild CTS	+	+
8-Mod CTS	+	+
9-Mod CTS	+	+
10-Mod CTS	−	−
11-Mod CTS	DNT*	(+)*
No. positive tests	5/6	4/6
Sham 2nd treatment		Posttest 2
1-Mild CTS	—	—
2-Mild CTS	(−)*	DNT*
3-Mild CTS	(+)*	DNT*
4-Mod CTS	+	+
No. positive tests	1/2	1/2
Pooled groups		
No. positive tests	6/8	5/8
McNemar test		z=.50
		P=.96

Abbreviations: +, positive test; −, negative test; DNT, did not test.
* Data excluded from McNemar comparisons.

median nerve sensory latencies after the sham treatment series (table 3). However, after the real treatment series (second series), there was a reduction in the sensory latency for each case. Case 7 had a prereal treatment sensory latency of 4.16ms and a postreal of 4.08ms; case 11 had a prereal sensory latency of 5.28ms and postreal of 4.8ms. Each of these placebo responders also had positive Phalen and Tinel signs postsham treatment but had negative signs postreal treatment. The overall placebo effect of 27.3% in this study is compatible with other controlled LLLT studies[30] that used sham laser to treat chronic pain (0%–54%).

In the present study, 7 of 8 patients (87.5%) receiving real LLLT plus microamps TENS on acupuncture points reported pain scores reduced by more than 50% postreal treatment (P=.0035). Postreal treatment, 6 of 8 cases (75%) reported MPQ scores ranging from 0 (n=4) to only 1 or 2 (n=2). The 2 patients (cases 9, 10) who reported postreal pain scores greater than 2 were moderate CTS cases. Case 9 reported a postreal pain score of 18, a 25% reduction from 24 (prereal). She was the only patient who had a history of amyloid, several years prior to entry. She was, however, satisfied with her outcome in this study, has remained employed, and has not required surgery. Case 10 reported a postreal pain score of 9, a 55% reduction from his prereal score of 20. He was the only patient who continued to smoke cigarettes throughout the study, and the only patient who reported a constant numbness in his fingertips, for at least 18 months before entry baseline.

All 11 patients resumed their previous work activities with less or no pain (eg, computer typist, handyman work with cement laying and electrical wiring, house painter, plumber). All but 1 patient (case 3) have remained stable in their pain reduction at 1 to 3 years follow-up. Case 3 (a placebo responder) was a 59-year-old woman who had had insulin-dependent diabetes mellitus since age 21 and had sustained a brainstem and left frontal lobe stroke that affected the CTS hand 2 years before her participation in this research. Her CTS pain returned within 1 year after completing the research treatments. Follow-up red-beam LLLT and microamps TENS self-administered treatments at home and steroid injection into the

Table 6: Tinel Sign

Cases	Pre	Post
Real 1st treatment	Entry Baseline	Posttest 1
1-Mild CTS	−	−
2-Mild CTS	+	−
3-Mild CTS	−	−
4-Mod CTS	+	−
No. positive tests	2/4	0/4
Real 2nd treatment		Posttest 2
5-Borderline/mild CTS	−	−
6-Mild CTS	+	−
7-Mild CTS	+	−
8-Mod CTS	−	−
9-Mod CTS	+	−
10-Mod CTS	−	−
11-Mod CTS	+	−
No. positive tests	4/7	0/7
Pooled groups		
No. positive tests	6/11	0/11
McNemar test		z=2.24
		P=.025
Sham 1st treatment	Entry Baseline	Posttest 1
5-Borderline/mild CTS	−	−
6-Mild CTS	−	+
7-Mild CTS	+	+
8-Mod CTS	−	−
9-Mod CTS	−	+
10-Mod CTS	−	−
11-Mod CTS	DNT*	(+)*
No. positive tests	1/6	3/6
Sham 2nd treatment		Posttest 2
1-Mild CTS	−	−
2-Mild CTS	(−)*	DNT*
3-Mild CTS	(−)*	DNT*
4-Mod CTS	−	−
No. positive tests	0/2	0/2
Pooled groups		
No. positive tests	1/8	3/8
McNemar test		z=1.06
		P=.29

* Data excluded from McNemar comparisons.

carpal canal failed to provide pain relief beyond a 3-month period in this case; she had both central and peripheral nervous system damage. Similar complications were observed in 1 CTS patient who later had a stroke in the open-protocol study of Branco and Naeser.[25] Case 4 completed the present study within 1 month of preparation of this article, and no long-term follow-up data were available.

The overall success rate of 87.5% in this controlled study is similar to that observed in uncontrolled studies that treated CTS pain. This includes studies that used needle acupuncture with 88% to 98% success rates,[21,22] or those using only LLLT with 77% to 91% success rates,[23,24] or a study that used needle acupuncture, LLLT, microamps TENS, plus other acupuncture therapies with a 92% success rate.[25]

Although an overall significant decrease was observed in the sensory latencies postreal treatment in the present study, no patient with abnormal sensory latency at entry baseline had normal sensory latency at posttest 2. Our NCSs were obtained, however, within 1 week after the last treatment in each treatment series (real and sham), and this may have been too soon for the sensory fibers to repair to normal.[54]

There was no significant improvement on the median nerve motor latencies after either the real or the sham treatment series; however, the posttreatment NCSs may have been obtained too early posttreatment (within 1wk), to show any effect on the motor latencies. For example, Harris et al,[54] who obtained follow-up NCSs in CTS cases who had undergone surgical release of the transverse carpal ligament, observed that "often a disturbance of conduction remained well past the time that objective and subjective complaints were cleared." In the Harris study,[54] patients with motor abnormalities had a more favorable result postsurgery than those with only sensory abnormalities. Often, there was a delay of 2 to 6 months or more before improvement or a return to normal was observed on the NCSs. In every instance in which postoperative NCSs were done, there was rapid subjective improvement postsurgery; however, the delay in improvement of the conduction velocity suggested that the reparative process in the nerves was slower. Harris did not have an explanation for this delay but suggested that, postsurgery, an ischemic process may be relieved in some fibers, and some other nerve fibers are slower in their recovery.

NCS and Electromyographic Data to Predict Candidacy and Outcome With LLLT and Microamps TENS

The results from the present study and the Branco and Naeser study[25] suggest that NCS and needle electromyographic data may be useful in predicting which CTS cases are likely to benefit from LLLT and microamps TENS stimulation of acupuncture points to treat CTS pain. In the Branco and Naeser study,[25] 33 of 36 hands were reported to have greater than 50% pain reduction after treatment with the same basic LLLT and microamps protocol that was used here. In that study, 2 of the 3 cases who did not achieve greater than 50% pain reduction posttreatment either had motor latency greater than 7ms (case 30, 7.08ms), or had evidence of axonal damage on needle electromyography (case 28). No severe cases of CTS (as defined by abnormality on electromyography) were treated in the present study.

Thus, the results from these 2 studies (total n=44; 3 placebo responders in present study omitted) suggest that mild-moderate CTS cases who have median nerve motor latencies as measured at standard distances, which are $\leq$7ms (sensory latencies may be absent), and who have no abnormality on electromyography, are good candidates for this type of treatment. It is likely that at least 87.5% of these CTS cases will have more than 50% pain reduction after this treatment protocol, and that 75% will likely have posttreatment pain scores of only 2 or less on the MPQ.

In the Branco and Naeser study,[25] this treatment protocol successfully reduced pain in 14 CTS patients who had not obtained satisfactory pain relief after 1 or 2 surgical release procedures of the transverse carpal ligament. Thus, in severe cases in which surgery has not provided satisfactory pain relief, this treatment protocol may be appropriate.

The significant improvement in median nerve sensory latencies after real LLLT and microamps TENS treatments in this study supports the significant improvements on NCSs after LLLT with CTS cases in the Weintraub study.[24] Energy densities (J/cm^2) were not reported by Weintraub, ruling out a comparison with those used in the present study. Weintraub reported only the joules per point (9J per each of 5 points).

The significant reduction in median nerve sensory latencies in the CTS cases postreal treatment in the present study also supports the significantly reduced latencies observed by Basford et al[55] in asymptomatic persons. In that study, an 830-nm laser was used at 1.2J per point. Other studies with asymptomatic persons, however, have found either no change or increased latencies after LLLT along the median or superficial radial nerve.[56-59]

Possible Mechanisms Underlying Improvement With LLLT and Microamps TENS

The physiologic mechanisms underlying significant decreases in most signs and symptoms of CTS after LLLT and microamps TENS in this study are unknown. Some possible mechanisms associated with LLLT were reviewed in the introduction. These included changes on the cellular level with increased ATP production by the mitochondria[37] and improved cellular respiration,[38] increased serotonin[39] and endorphins,[40] decreased inflammation,[41,42] and improved local blood circulation.[33,43] An increase in ATP on the cellular level has also been suggested as a mechanism for effectiveness with microamps TENS.[49]

Potential Cost Savings

The current estimate to treat 1 case of CTS without surgical intervention in the United States is around $5246.[18] The cost to treat 1 case of CTS with the LLLT and microamps TENS stimulation of acupuncture points is about $1000 ($65 per office visit for 15 visits=$975). Thus, there is a potential savings of at least $4000 per mild to moderate CTS case. Supplemental home treatments[19,60] are also possible with an equipment cost of around $550. (The cost of a 5-mW red-beam laser diode is about $150, cost of the microamps TENS device used here, $400.)

CONCLUSIONS

Weintraub[24] concluded that LLLT appears to be an attractive substitute for surgery. Our results support his conclusion, especially when this new conservative treatment is applied in the earlier stages of CTS (preferably within 1y of symptom onset) and with mild to moderate cases (as defined with NCSs and where there is no abnormality on needle electromyography). Based on these initial positive results, further research with LLLT and microamps TENS to treat a larger number of CTS cases who meet these criteria would be appropriate. A total of 15 treatments is recommended.[25]

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Suppliers

a. TECA Corp, 4048 W Schubert Ave, Chicago, IL 60639.
b. SHARN Inc, 4801 George Rd, Ste 180, Tampa, FL 33634.
c. Model 1620; Dynatronics Corp, 7030 Park Centre Dr, Salt Lake City, UT 84121.
d. Model 2400; Respond Systems Inc, 20 Baldwin Dr, Branford, CT 06405.
e. Model 100; MicroStim Inc, 7881 NW 90th Ave, Tamarac, FL 33321.