**Study Summary**
The attached is a study is on the use of dual modality of LLLT and MET from 1999 in the treatment of carpal tunnel syndrome.

**Summary of attached study:**
Carpal Tunnel Syndrome: Clinical Outcome after Low-Level Laser Acupuncture, Microamps Transcutaneous Electrical Nerve Stimulation, and Other Alternative Therapies-An Open Protocol Study
Kenneth Branco M.A. Lic. Ac. and Margaret A. Naeser, Ph.D. Lic. Ac., Dipl. Ac. (NCCAOM)

This is a 1999 Open Treatment Protocol, which means that it cannot be done blind, i.e. the patients can see and feel what is going on. Thirty six hands were used. This studies course of treatment was over a 4-5 week period with 12-15 treatments lasting 45 minutes each. There was a significant reduction of pain for 91.6% of the participants from no pain to more than 50% reduction.

The goal was to measure pain reduction and longevity of this reduction with patients (who previously failed standard medical/surgical treatments) using noninvasive techniques utilizing red-beam low-level laser and microamps transcutaneous electrical nerve stimulation (TENS). There were other alternative therapies however the two modalities mentioned above were considered the “Primary” treatment modalities because they were the two treatments that were used on every single patient in the same manner.

Not only did the patients experience pain relief there is a documented cost savings as well. The estimated cost at the time was that per case it cost average of $12,000 and the treatment cost studied was $1000. This study was at the time the only study to do a follow up at 1 and 2 years to see how the patients were doing and what their experience had been. Only two patients had pain return and they were treated again and in a few weeks experienced pain relief again.
Carpal Tunnel Syndrome: Clinical Outcome After Low-Level Laser Acupuncture, Microamps Transcutaneous Electrical Nerve Stimulation, and Other Alternative Therapies—An Open Protocol Study

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ABSTRACT

Objective: Outcome for carpal tunnel syndrome (CTS) patients (who previously failed standard medical/surgical treatments) treated primarily with a painless, noninvasive technique utilizing red-beam, low-level laser acupuncture and microamps transcutaneous electrical nerve stimulation (TENS) on the affected hand; secondarily, with other alternative therapies.

Design: Open treatment protocol, patients diagnosed with CTS by their physicians.

Setting: Treatments performed by licensed acupuncturist in a private practice office.

Subjects: Total of 36 hands (from 22 women, 9 men), ages 24–84 years, median pain duration, 24 months. Fourteen hands failed 1–2 surgical release procedures.

Intervention/Treatment: Primary treatment: red-beam, 670 nm, continuous wave, 5 mW, diode laser pointer (1–7 J per point), and microamps TENS (<900 μA) on affected hands. Secondary treatment: infrared low-level laser (904 nm, pulsed, 10 W) and/or needle acupuncture on deeper acupuncture points; Chinese herbal medicine formulas and supplements, on case-by-case basis. Three treatments per week, 4–5 weeks.

Outcome Measures: Pre- and posttreatment Melzack pain scores; profession and employment status recorded.

Results: Posttreatment, pain significantly reduced (p < .0001), and 33 of 36 hands (91.6%) no pain, or pain reduced by more than 50%. The 14 hands that failed surgical release, successfully treated. Patients remained employed, if not retired. Follow-up after 1–2 years with cases less than age 60, only 2 of 23 hands (8.3%) pain returned, but successfully re-treated within a few weeks.

Conclusions: Possible mechanisms for effectiveness include increased adenosine triphosphate (ATP) on cellular level, decreased inflammation, temporary increase in serotonin. There are potential cost-savings with this treatment (current estimated cost per case, $12,000; this treatment, $1,000). Safe when applied by licensed acupuncturist trained in laser acupuncture; supplemental home treatments may be performed by patient under supervision of acupuncturist.

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INTRODUCTION

Carpal Tunnel Syndrome (CTS) is an entrapment neuropathy of the median nerve at the wrist, due to compression of the median nerve as it passes from the forearm to the palm, beneath the transverse carpal ligament (Stevens, 1997). A consensus on diagnostic criteria for CTS is lacking (Dawson, 1993; Stevens, 1997). However, there are specific signs and symptoms associated with CTS, including paresthesias, numbness and tingling in the sensory distribution of the median nerve for thumb, index, middle, and radial side of ring finger, Tinel sign, Phalen sign, hypoaesthesia, nocturnal awakening, specific pain diagrams for the hand, and sometimes hand weakness (Matte et al., 1989; Katz et al., 1990; Dawson, 1993; Hennessey and Kuhlman, 1997). Nerve conduction studies (NCSs) are the primary definitive test, although test results considered to be compatible with CTS vary somewhat across studies (Stevens, 1987; Feldman et al., 1987; AAEM Quality Assurance Committee, Jablecki et al., 1993; Stevens, 1997; Vennix et al., 1998).

The etiology is unknown, however, CTS occurs more commonly in workers whose tasks involve repetitive hand movements, such as computer keyboard typing, operating machinery, and assembly line work. Overuse syndrome (cumulative trauma syndrome, repetitive strain injury [RSI]) has accounted for more than 50% of all occupational illnesses in the United States (Rempel et al., 1992); it may be a result of concentration of the workload on a few smaller groups of muscles (Dawson, 1993). CTS may be a minority of the cases of overuse syndrome, however, “collection of relevant data has been hampered by the lack of consensus among researchers in the field.” (Dawson, 1993, Stock, 1991).

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 non-steroidal anti-inflammatory drugs (NSAIDs) (Feldman et al., 1987; Mackinnon and Novak, 1994).

Direct injection of steroids into the carpal tunnel may provide relief for only 2–4 months (Slater and Bynum, 1993); and at 18 months only 22% of patients may be free of symptoms (Gelberman et al., 1980).

Surgical release of the transverse carpal ligament is performed in approximately 40% of CTS cases, with estimates of more than 460,000 procedures performed each year, and a direct medical cost of over $1.9 billion (Levine et al., 1993; Palmer and Hanrahan, 1995). Good-to-excellent results for pain relief are observed in 80% of these cases, however, only 40% regain normal function; 5% worsen (Cseuz et al., 1966; Armstrong and Villalobos, 1997). Office workers return to work in a few weeks; those working in heavier labor require 4–6 months of rehabilitation.

CTS requires, on average, the longest recuperation period of all injuries or illnesses that require days away from work (Brogmus and Marko, 1990). In 1995, half of all workers afflicted with CTS missed 30 days or more of work (BLS Reports, 1995). According to data from one state (Washington State Department of Labor & Industries) in 1992–1994, occupational CTS averaged 2.9 per 1000 workers per year (Daniell et al., 1998). “Two-thirds (67%) received compensation for... median, 119 lost work days... and 27% for permanent partial disability. Cumulative medical and disability compensation costs during 1986–1994 (in Washington state) were $158- and $225 million dollars.” (Daniell et al., 1998).

In 1996, the estimated incidence in the United States was 2 million cases (Brody, 1996). The National Council of Compensation Insurance finds the average claim for CTS to be $29,000, with the full cost being $100,000 if lost productivity is taken into account (BLS Reports, 1995). In 1993, the cost to treat one case of CTS without surgery in California was $5,246, and with surgery, $20,925 (CTDNEWS, 1995). The average cost to treat one case of CTS nationwide is about $12,000 (Clairmont, 1997); the total cost in 1 year could be as high as $12 to $24 billion.

There is need for new, less expensive and more cost-effective, conservative treatments for CTS/RSI. This article presents clinical outcome
data for CTS cases treated with a new, alternative treatment program using primarily two, noninvasive, painless, treatment modalities, eg, red-beam laser and microamps transcutaneous electrical nerve stimulation (TENS), to stimulate acupuncture points on the affected hands (Naeser and Wei, 1994; Naeser, Hahn and Lieberman, 1996; Naeser et al., 1997). In addition, other secondary, Oriental medicine treatment modalities were used, including stimulation of deeper acupuncture points on the posterior neck, shoulder, and elbow area with infrared-beam laser and/or needle acupuncture, moxibustion, Chinese herbal medicine formulas and/or supplements. As is common practice in traditional Chinese medicine (TCM), each patient was treated with an individually determined treatment protocol. The single common treatment that every patient received was the stimulation of hand acupuncture points with red-beam laser and microamps TENS. The other secondary, Oriental medicine therapies varied from case to case, as determined by TCM diagnosis (utilizing palpation, pulse diagnosis, tongue diagnosis, and patient history). This article presents information on how low-level laser acupuncture, microamps TENS, and other alternative treatment modalities were used to treat a series of CTS patients who had failed to obtain pain relief after standard medical/surgical treatments for CTS.

RATIONALE FOR LOW-LEVEL LASER ACUPUNCTURE TO TREAT CTS PAIN

Since the early 1980s, low-level lasers have been used anecdotally to stimulate acupuncture points (instead of needles) to help treat pain (Kleinkort and Foley, 1984). Low-level laser acupuncture also has been used to help treat paralysis and spasticity in adult stroke patients (Naeser et al., 1995), and cerebral palsy in babies and children (Lidicka and Hegyi, 1994; Asagai et al., 1994); its wide variety of uses is reviewed by Naeser and Wei (1994). The use of low-level laser to promote wound healing and treat a variety of pain disorders has produced variable results (there are no definitive guidelines yet determined for ideal wavelength of the laser beam, power of the laser output, number of joules, frequency of treatments, etc.); these topics have been reviewed by Basford (1989; 1993).

Low-level laser stimulation is noninvasive, and it produces no feeling when applied to the skin—no heat, no cold, no pain. The high-level, cutting lasers used in surgery are around 300 W. Low-level lasers in the range of 5–500 mW are classified by the Food and Drug Administration (FDA) as class IIIb lasers (U.S. Department HHS, 1985). When used within FDA safety guidelines (not shown directly into the eyes), and approved by an Institutional Review Board, low-level laser studies are considered to be “Nonsignificant Risk Device Studies” (FDA, 1986, p. 7–96).

EFFECT OF LOW-LEVEL LASER ON THE CELLULAR LEVEL

While the mechanisms through which laser stimulation affects cells are not completely understood, research on this has been underway with low-level, red-beam, helium neon (HeNe) laser since the 1960s (Mester et al., 1967; Gamaley, 1977; Mester et al., 1982; Mester et al., 1985; Karu, 1987), and reviewed by Basford (1989; 1993). There is an optical window between 600 and 1300 nm wavelength (red-beam to near-infrared), for laser penetration into human skin (Anderson and Parrish, 1981). Red-
beam laser light appears to have a shallow penetration, 0.8-mm direct energy (Seitz and Kleinkort, 1986), whereas lasers in the infrared range have a deeper penetration, up to 1.5 inches (Seitz and Kleinkort, 1986; Hudson, 1997). As the laser beam passes through tissue, however, it is rapidly reduced in its incident intensity. For example, with red-beam laser, the incident intensity may be only 37%, within only a few millimeters. However, with infrared laser, the penetration may be several millimeters more (Basford, 1993; Kolari, 1985; Anderson and Parrish, 1981). Hudson (1997) has observed a 904-nm infrared laser beam to be detectable at greater than 50% output power, at 1-inch depth penetration in bovine muscle tissue (10 W, pulsed at 3500 pulses per second (pps); Respond Systems model 2400, Branford, CT). The low-level laser effects are not based on thermal mechanisms; there is perhaps no more than a 0.1°C to 0.75°C increase (Basford, 1989; 1993; Walsh et al., 1995).

Basic research with red-beam, low-level laser has observed the following effects on the cellular level in rat liver mitochondria (Passarella, 1989): (1) The optical properties of mitochondria are influenced by HeNe laser irradiation (Passarella et al., 1983). (2) Adenosine triphosphate (ATP) extrasyntesis occurs in mitochondria after HeNe laser irradiation (Passarella et al., 1984; Passarella et al., 1987). (3) Laser irradiation generates new mitochondrial conformations as revealed by electron microscopy studies (Passarella et al., 1988). (4) Oxygen consumption has been observed to significantly increase with a 660-nm laser, 10 mW/cm² output (at 0.6 J/cm² and 1.2 J/cm²) (Yu et al., 1997). Other significant cellular changes were also observed including increased phosphate potential and energy charge (at 1.8 J/cm² and 2.4 J/cm²) in the Yu et al. (1997) study.

OTHER POSSIBLE EFFECTS OF LOW-LEVEL LASER

Low-level laser biostimulation may have an anti-inflammatory effect. Goldman et al. (1980) observed an anti-inflammatory effect in rheumatoid arthritis; a decreased level of circulating immune complexes as measured by platelet aggregation was observed during the use of real (not sham) laser. Palmgren et al. (1989), also working with rheumatoid arthritis cases, observed real laser treatments with an 820-nm infrared diode laser on the finger joints, as well as sham laser treatments, to significantly decrease pain; however, only those patients receiving the real treatments also showed a significant trend toward decrease in sedimentation rate and number of leukocytes.

Walker (1983) has suggested that HeNe laser affects serotonin metabolism, because a large increase in urinary excretion of 5-hydroxyindoleacetic acid was noted after 10 red-beam, HeNe laser treatments, in patients who were successfully treated for chronic pain after 30 treatments, in a placebo-controlled, double-blind study. Sham stimulation had no effect.

Walker and Akhanjee (1985) have suggested that because low-level laser produces no detectable thermal change, it may be photochemical reactions that alter neuronal activity. Photons may interact with chromophores (optically active molecules) on nerve membrane (Anderson and Parrish, 1982; Regan and Parrish, 1982; Smith, 1980). Walker and Akhanjee (1985) also mention that alternatively, light may interact with rhodopsin kinase or a rhodopsin kinase-like protein that occurs in different areas of the nervous system (Somers and Klein, 1984).

EFFECT OF LOW-LEVEL LASER ON NERVE CONDUCTION

The effect of low-level laser irradiation on the conduction velocity of the median or superficial radial nerve in asymptomatic human volunteers has been examined with conflicting results. Snyder-Mackler and Bork (1988) reported a significant increase in latency in the superficial radial nerve compared to placebo (p < .01) using red-beam, HeNe laser at 19 mJ/cm². Basford et al. (1993), however, using 830-nm (near-infrared) at 1.2 J per point, observed a significant decrease (p < .016, p < .046) in motor and sensory distal latencies (DL) respectively, relative to placebo control. Other studies with 830-nm laser, especially at 1.5 J/cm², have shown
significant increases in antidromic conduction latencies (Baxter et al., 1994; Lowe et al., 1994).

LOW-LEVEL LASER TO TREAT CTS PAIN

In an uncontrolled study with open protocol, 23 cases with CTS (30 hands) were treated with 830 nm, 30 mW laser (9 J per point), at 5 points along the median nerve at the wrist/hand (Weintraub, 1997). A normalization of DL compound muscle action potential (CMAP) in 11 hands and tendency to improve in 23.4% was observed, reversing CTS in 77% of cases. Also in a separate uncontrolled study, with 35 CTS/RSI cases, using 830 nm, 100 mW laser (12–30 J per point), Wong et al. (1995) successfully treated 91.4% of cases by treating only at the posterior neck region (C5-T1, not the wrist/hand) over an 8-month period (10 treatments). No NCS data were included in the Wong et al. (1995) study.

Rationale for microamps TENS to treat CTS pain

Most standard TENS devices use milliamps, and the patient feels a tingling sensation under the TENS pads. Milliamps TENS is believed to reduce pain, in part, through the Gate Control Theory (Melzack and Wall, 1965). Microamps TENS is different and the patient feels nothing.

Effects of Microamps on the Cellular Level. Microamps stimulation has been observed to have an effect on adenosine triphosphate (ATP) concentrations and protein synthesis on the cellular level in rat skin (Cheng et al., 1982). In the Cheng study, ATP concentrations were increased by as much as 300% to 500% in cells stimulated with constant currents between 25 µA and 1000 µA; the greatest stimulatory effects were obtained around 500 µA. Currents greater than 1.5 mA can decrease the ATP concentrations, and decrease the protein synthesis and transmembrane movement of metabolites (Cheng et al., 1982). Standard TENS devices operate in the 20 to 80 mA and higher ranges; levels that may deplete the cell’s ATP and metabolic processing capabilities. Microamps stimulation has been used in a double-blind study to successfully treat chronic low back pain with 40 patients where each patient received a total of 16 treatments (Meyer and Nebronsky, 1983).

Real versus sham laser acupuncture and microamps TENS to treat CTS pain

A treatment protocol using red-beam, low-level laser and microamps TENS to stimulate hand acupuncture points to treat CTS pain was developed in 1990 (Naesser and Wei, 1994, pp. 40, 94). A pilot research project has been in progress at the Department of Veterans Affairs Medical Center, Boston, Massachusetts, and the Department of Neurology, Boston University School of Medicine, Boston, Massachusetts, since 1994, where real versus sham laser acupuncture and microamps TENS are used to treat CTS/RSI pain (Naesser et al., 1996; Naesser, 1997a).

It is possible to conduct controlled research with low-level laser and microamps TENS because each device produces no feeling—no heat, no cold, no pain. The patient’s hand is treated behind a hanging black curtain, and the patient is not aware whether either device is turned on, or off. The research protocol uses a continuous-wave, 15-mW, 632.8-nm, red-beam laser (HeNe; Dynatronics model 1620, Salt Lake City, UT); a pulsed, 10 W, gallium arsenide, 904-nm, infrared diode laser (Respond Systems model 2400, Branford, CT); and a microamps TENS (<900 µA, MicroStim model 100, MicroStim, Tamarac, FL). The 15-mW HeNe laser has a 2-mm diameter probe tip used to stimulate acupuncture points (66.6 seconds equal 1 J; 2.07 seconds equal 1 J/cm² energy density; it is a class IIIb laser. The pulsed, 10-W infrared diode laser utilizes a pulse width of 180 nanoseconds “on” time. There are six different pulse frequencies, ranging from 73 pps to 3500 pps. At 3500 pps, the milliwatt equivalent output is only 5.92 mW. The fiberoptic cable has a 5-mm diameter probe tip used to stimulate acupuncture points (at 3500 pps, 168.9 seconds equal 1 J; and 33.1 seconds equal 1 J/cm²). This pulsed, 10-W laser is a class IIIb laser; it will not burn the skin. All devices are donated on consignment, by the companies that produce them.

Overall, 10 cases (10 hands) have been treated in this ongoing research (8 men, 2 women; ages 40–68 years, mean 52.7 years, SD,
The duration of hand pain ranged from 3 to 30 months, mean, 14.6 months, SD, 10.6; median, 15 months). The pretreatment nerve conduction study data showed the cases to have only mild/moderate CTS, ie, the motor distal latencies were 6.5 ms or less, and the sensory latencies were 4.4 ms or less \((n = 7)\), or absent \((n = 3)\). No severe CTS cases with abnormal electromyogram were included.

The low-level laser acupuncture and microamps TENS treatment protocol (number of joules and treatment times) used in the controlled research is similar to the treatment protocol in the present clinical outcome report (explained below, under Treatment Method). Briefly, the red-beam laser and microamps TENS were used on the affected hand; and the infrared laser was used on deeper acupuncture points on the posterior neck, shoulder and elbow areas. Patients felt no stimulation during any of the treatments (real or sham).

The shallow acupuncture points on the hand were treated with the 15 mW red-beam laser while the patient was seated at a table and the hand was placed behind a hanging black curtain. Most of these shallow points were treated with 1 J per point (66.6 seconds; or 33.2 J/cm²). The deeper acupuncture points on the posterior neck, shoulder and elbow were treated with invisible infrared laser that, of course, the patient could not see, even during the real infrared laser beam emission. Using the 10W pulsed infrared laser, the deeper acupuncture points were treated first with a higher frequency pulse rate (3500 pps for 1 minute, 1.8 J/cm²), then at lower frequency pulse rates for a few minutes (584 pps for 1 minute, 0.3 J/cm²; and 73 pps for 1 minute, 0.04 J/cm²). Treatment times varied from case-to-case depending on the type and location of pain. Patients were treated three times a week (every other day); they received about 1 month of real or sham treatments, with a cross-over design for 1 more month of treatments. All cases received a series of real and sham treatments. The persons obtaining the Melzack pain scores and the Nerve Conduction Study data were blind as to which treatment condition the patient had just completed. No additional Oriental medicine treatment modalities were used with these research subjects.

There was a significant reduction in the Melzack pain scores after the real treatments \((p = .0048)\), but not after the sham. The mean Melzack pain score, pre-real treatment was 17.5 (SD, 11.5); the mean Melzack pain score, post-real treatment was 4.1 (SD, 6.0). The mean Melzack pain score, pre-sham treatment was 14.6 (SD, 11.2); the post-sham mean was 11.4 (SD, 13.7).

There was a significant decrease in the median nerve, sensory latency after the real treatments \((p = .006)\), but not after the sham treatments. The mean sensory latency, pre-real treatment was 3.98 (SD, 0.72); the mean sensory latency, postreal treatment was 3.73 (SD, 0.68). The mean sensory latency, pre-sham treatment was 4.09 (SD, 0.58); the post-sham mean was 4.07 (SD, 0.66). There was no significant decrease in the median nerve, motor latency after either the real treatments or the sham treatments.

All 10 patients were able to resume prior work with less or no pain including computer keyboard, handyman (cement laying, electrical wiring), house painter, plumber. All cases have remained stable in their pain reduction at 1–3 years follow-up, except for one case.\(^1\) This controlled research project is continuing.

**METHODS**

**Subjects**

A total of 36 hands were treated in this clinical outcome report. There were 31 CTS cases (22 females, 9 males) (Table 1). The age at entry ranged from 24–84 years (mean, 55.2, SD,

\(^1\)This complex case was a 59-year-old woman who had had insulin-dependent diabetes since age 21; she had sustained a brain stem and left frontal lobe stroke affecting the CTS hand 2 years prior to the laser acupuncture treatments. Her CTS pain returned within 1 year after completion of laser acupuncture treatments, and although some follow-up treatments initially relieved the pain for 3 more months, these treatments became ineffective. Subsequent steroid injection into the carpal canal also failed to provide pain relief beyond a 3-month period.
18.9; median, 50 years). All cases had previously received standard medical treatment without successful pain relief. This included NSAIDs and wrist splints. Also, 17 of 36 hands (47.2%) had been treated with 1–3 cortisone injections; and 14 of 36 hands (38.8%) had received 1–2 surgeries for release of the transverse carpal ligament. The duration of pain prior to this new alternative treatment program ranged from 2 months to 18 years; median, 24 months. The diagnosis of CTS had been made by the patients’ physicians. Data from nerve conduction study (NCS) and electromyography (EMG) were available for 6 cases (all in the older age group, >60 years of age) (Table 1).

Stevens (1997) has stated that there is no universally agreed on standard for the diagnosis of CTS, or method of grading the severity of CTS; rather a combination of clinical and electrodiagnostic information should be used. With this caveat in mind, electrodiagnostic standards from a variety of sources (Feldman et al., 1987; Stevens, 1997; Vennix et al., 1998) were used to define severity of CTS, as follows: borderline/mild CTS: 4.3 ms median nerve, motor DL across the carpal tunnel; and 3.4 ms median nerve, sensory latency; moderate CTS: greater than 4.3 ms to 7.0 ms, motor DL, and 3.4 ms or more, median nerve, sensory latency; and severe CTS: greater than 7.0 ms, motor DL, or evidence of denervation on electromyogram.

Treatment Method

All treatments were performed by K.B. with open protocol in the acupuncture office. Prior to the first treatment and immediately after the last treatment, each patient was administered the McGill-Melzack Pain Questionnaire (Melzack, 1975). Signed, informed consent was obtained. Patients were treated every other day on a Monday, Wednesday, Friday schedule; or on a Tuesday, Thursday, Saturday schedule, for 4–5 weeks (12–15 treatments). Each treatment lasted 45 minutes.

The two treatment modalities (red-beam laser and microamps TENS) that were applied on the affected hands in the research program at the Boston D.V.A. Medical Center, were also applied on the affected hands in this clinical study, with the same treatment protocol. These two modalities were considered to be the primary treatment modalities in this open-protocol clinical study, because these two devices were used in an identical manner on all cases. The other secondary modalities (explained later) were added and adjusted on a case-by-case basis.

A less expensive red-beam laser was used in this open-protocol, clinical study. Instead of using the 15-mW, 632.8-nm, gas tube HeNe laser, an inexpensive, continuous-wave, 5-mW, 670-nm, red-beam, diode laser lecture pointer (LP 5F1, ITO brand) was used (Naeser and Wei, 1994; Naeser et al., 1997). The 5-mW laser pointer had an aperture of 5-mm diameter. The laser pointer was placed directly over each acupuncture point on the skin. The 5-mW laser required a total of 200 seconds to produce 1 J (39.2 seconds equals 1 J/cm² energy density). As a practical matter for use in the clinic, a time of 3 minutes was used (180 seconds) as an approximate time for 1 J (0.9 J). Most acupuncture points on the hand were treated with 1 J (4.6 J/cm²). There were three steps to this primary portion of this alternative treatment program:

Step 1. laser applied to the wrist. The tip of the laser pen was physically placed onto the skin at the median nerve area at the center of the distal wrist crease (acupuncture point, Pericardium 7) for approximately 21 minutes (6–7 J); a total of 21 minutes (1260 seconds) equals 6.3 J (32.1 J/cm²).

Step 2. microamps TENS applied to the wrist. The MicroStim 100 TENS device has two electrodes—a primary electrode and a grounding pad. The primary electrode is a metallic, circular-shaped electrode with four small (2-mm

Low-level laser biostimulation for treatment of pain is considered Investigational by the FDA. The licensed acupuncturist is registered with an Independent Institutional Review Board for Laser Acupuncture Research. No medical claims are made. The laser beam is never shown directly into the eyes. The microamps TENS device is not used with pregnant women, or with patients who have a pacemaker.
## Table 1. Data for 31 Carpal Tunnel Syndrome Cases (36 Hands) Treated with Laser Acupuncture, Microamps TENS and Other Alternative Therapies (Patients are Rank-Ordered by Age at Entry into this Treatment Program)

<table>
<thead>
<tr>
<th>Case no.</th>
<th>Age at entry and sex</th>
<th>No. of cortisone injections</th>
<th>Previous surgery</th>
<th>Duration of pain prior to laser acupuncture</th>
<th>Melzack pain score before laser acupuncture</th>
<th>Melzack pain score after laser acupuncture</th>
<th>No. of laser acupuncture treatments</th>
<th>Hand(s) treated</th>
<th>Profession</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>24, f</td>
<td>0</td>
<td>No</td>
<td>3 months</td>
<td>28</td>
<td>0</td>
<td>5</td>
<td>Right</td>
<td>Secretary</td>
<td>Workmen's compensation Case, Returned to work, full-time</td>
</tr>
<tr>
<td>2</td>
<td>26, m</td>
<td>0</td>
<td>No</td>
<td>8 months</td>
<td>29</td>
<td>29</td>
<td>12</td>
<td>Right and left</td>
<td>Repair service</td>
<td>Continued working</td>
</tr>
<tr>
<td>3</td>
<td>27, f</td>
<td>x1, R</td>
<td>Yes, x1, R</td>
<td>2 years</td>
<td>16</td>
<td>0</td>
<td>12</td>
<td>Right</td>
<td>Maintenance worker</td>
<td>Required 9 f/u treatments after 4-5 months</td>
</tr>
<tr>
<td>4</td>
<td>31, m</td>
<td>x1, L</td>
<td>No</td>
<td>1 year</td>
<td>36</td>
<td>0</td>
<td>12</td>
<td>Left</td>
<td>Retail manager</td>
<td>Continued working</td>
</tr>
<tr>
<td>5</td>
<td>31, m</td>
<td>0</td>
<td>No</td>
<td>3 years</td>
<td>33</td>
<td>0</td>
<td>12</td>
<td>Right</td>
<td>Auto-Body mechanic</td>
<td>Continued working</td>
</tr>
<tr>
<td>6</td>
<td>34, f</td>
<td>0</td>
<td>Yes, x1, R</td>
<td>6 years</td>
<td>32</td>
<td>0</td>
<td>15</td>
<td>Right</td>
<td>Secretary</td>
<td>CT release, postsurgical site pain, and thoracic outlet syndrome pain also treated</td>
</tr>
<tr>
<td>7</td>
<td>38, f</td>
<td>0</td>
<td>No</td>
<td>5 months</td>
<td>32</td>
<td>0</td>
<td>15</td>
<td>Left</td>
<td>Housewife, teacher</td>
<td>Continued working</td>
</tr>
<tr>
<td>8</td>
<td>45, f</td>
<td>x1, R</td>
<td>Yes, x1, R</td>
<td>7 months</td>
<td>36</td>
<td>0</td>
<td>15</td>
<td>Right</td>
<td>Computer operator</td>
<td>Workmen's compensation case, Returned to work, part-time</td>
</tr>
<tr>
<td>9</td>
<td>46, f</td>
<td>x1, R, x1, L</td>
<td>Yes, x1, R</td>
<td>3 years</td>
<td>41</td>
<td>0</td>
<td>15</td>
<td>Right and left</td>
<td>Secretary</td>
<td>Continued working</td>
</tr>
<tr>
<td>10</td>
<td>46, f</td>
<td>0, L</td>
<td>Yes, x1, R</td>
<td>7 months</td>
<td>26</td>
<td>22</td>
<td>15</td>
<td>Right and left</td>
<td>Computer operator</td>
<td>Workmen's compensation case, Returned to work, part-time</td>
</tr>
<tr>
<td>11*</td>
<td>47, m</td>
<td>0</td>
<td>No</td>
<td>2 years</td>
<td>28</td>
<td>20</td>
<td>15</td>
<td>Right</td>
<td>Computer operator</td>
<td>Weightlifter; continued to lift weights throughout treatments; continued working</td>
</tr>
<tr>
<td>ID</td>
<td>Age</td>
<td>Sex</td>
<td>Hand</td>
<td>Duration</td>
<td>Symptoms</td>
<td>Ongoing</td>
<td>Occupation</td>
<td>Notes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----</td>
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<td>---------</td>
<td>------------</td>
<td>-------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>48</td>
<td>f</td>
<td>0</td>
<td>5 years</td>
<td>47</td>
<td>0</td>
<td>12</td>
<td>Right and left</td>
<td>Nurse's aid</td>
<td>Continued working</td>
</tr>
<tr>
<td>13</td>
<td>48</td>
<td>f</td>
<td>0</td>
<td>1 year</td>
<td>42</td>
<td>0</td>
<td>15</td>
<td>Right</td>
<td>Artist, painter</td>
<td>Continued working</td>
</tr>
<tr>
<td>14</td>
<td>49</td>
<td>f</td>
<td>x1, R</td>
<td>x1, L</td>
<td>1 year</td>
<td>27</td>
<td>0</td>
<td>Right and left</td>
<td>Nail technician</td>
<td>Continued working</td>
</tr>
<tr>
<td>15</td>
<td>49</td>
<td>m</td>
<td>0</td>
<td>2 years</td>
<td>8</td>
<td>0</td>
<td>12</td>
<td>Right</td>
<td>Photographer</td>
<td>Continued working</td>
</tr>
<tr>
<td>16</td>
<td>50</td>
<td>f</td>
<td>0</td>
<td>2 months</td>
<td>34</td>
<td>0</td>
<td>12</td>
<td>Left</td>
<td>Housewife</td>
<td>Hands cold, pretreatment. Circulation better, posttreatment</td>
</tr>
<tr>
<td>17</td>
<td>53</td>
<td>f</td>
<td>x2, R</td>
<td>No</td>
<td>2 years</td>
<td>2</td>
<td>0</td>
<td>Right</td>
<td>Factory worker, packaging/wrapping</td>
<td>Pretreatment, only intermittent numbness Workmen's compensation case. Returned to work, full-time</td>
</tr>
<tr>
<td>18</td>
<td>54</td>
<td>f</td>
<td>x1, R</td>
<td>x1, R</td>
<td>5 years</td>
<td>41</td>
<td>12</td>
<td>Right</td>
<td>Office manager</td>
<td>Continued working</td>
</tr>
<tr>
<td>19</td>
<td>56</td>
<td>f</td>
<td>0</td>
<td>6 months</td>
<td>39</td>
<td>0</td>
<td>12</td>
<td>Right</td>
<td>Proprietor, ice cream server</td>
<td>Hands cold, pretreatment. Circulation better, posttreatment Continued working</td>
</tr>
<tr>
<td>20</td>
<td>65</td>
<td>f</td>
<td>x2, L</td>
<td>No</td>
<td>6 years</td>
<td>28</td>
<td>0</td>
<td>Left</td>
<td>Retired (machine operator)</td>
<td>Mot. Lat., 5.3 ms, Dupuytren's Contracture 4th digit; Diabetic</td>
</tr>
<tr>
<td>21</td>
<td>66</td>
<td>m</td>
<td>x3, L</td>
<td>No</td>
<td>7 years</td>
<td>48</td>
<td>14</td>
<td>Left</td>
<td>Retired, now lobsterman as hobby</td>
<td>Required 6 f/u treatments after 3 months</td>
</tr>
<tr>
<td>22</td>
<td>66</td>
<td>f</td>
<td>1x, R</td>
<td>x1, R</td>
<td>2 years</td>
<td>42</td>
<td>2</td>
<td>Right</td>
<td>Retired factory worker</td>
<td>Sens. Lat. 3.65 ms; Mot. 3.75 ms Required 6 f/u treatments after 2 months; cervical compression, 3 infrared laser treatments on neck, pain 0</td>
</tr>
</tbody>
</table>

(continued)
<table>
<thead>
<tr>
<th>Case no.</th>
<th>Age at entry and sex</th>
<th>No. of cortisone injections</th>
<th>Previous surgery</th>
<th>Duration of pain prior to laser acupuncture</th>
<th>Melzack pain score before laser acupuncture</th>
<th>Melzack pain score after laser acupuncture</th>
<th>No. of laser acupuncture treatments</th>
<th>Hand(s) treated</th>
<th>Profession</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>75, f</td>
<td>x2, R</td>
<td>Yes, x1, R</td>
<td>2 years</td>
<td>39</td>
<td>10</td>
<td>15</td>
<td>Right</td>
<td>Retired</td>
<td>(store manager) Sens. Lat., Absent; Mot. 4.3 ms</td>
</tr>
<tr>
<td>24</td>
<td>75, f</td>
<td>0</td>
<td>No</td>
<td>1.5 years</td>
<td>20</td>
<td>10</td>
<td>15</td>
<td>Right</td>
<td>Retired</td>
<td>Cervical spine, severe degenerative changes, bilateral osteophyte encroachment on several neural foramina</td>
</tr>
<tr>
<td>25</td>
<td>76, m</td>
<td>x1, R</td>
<td>Yes, x1, R</td>
<td>18 years</td>
<td>51</td>
<td>0</td>
<td>12</td>
<td>Right</td>
<td>Retired</td>
<td>Mild thenar atrophy. Required 2 f/u treatments 6 months later, 2 months after coronary bypass surgery</td>
</tr>
<tr>
<td>26</td>
<td>78, m</td>
<td>0</td>
<td>No</td>
<td>1 year</td>
<td>25</td>
<td>0</td>
<td>15</td>
<td>Right</td>
<td>Retired</td>
<td>Within a month, required 6-8 f/u treatments for residual numbness, which was resolved</td>
</tr>
<tr>
<td>27</td>
<td>80, f</td>
<td>0</td>
<td>No</td>
<td>3 years</td>
<td>33</td>
<td>0</td>
<td>12</td>
<td>Right</td>
<td>Retired</td>
<td>Osteoarthritis pain, finger joints improved</td>
</tr>
<tr>
<td>28*</td>
<td>81, m</td>
<td>0</td>
<td>No</td>
<td>3 years</td>
<td>30</td>
<td>30</td>
<td>15</td>
<td>Right</td>
<td>Retired</td>
<td>Sens. Lat., Absent; Mot., 4.6 ms. Low amp., CMAP 2.1; Borderline slow cond. vel. 48.0 m/s; 2+ fibrils and decreased numbers of mod. enlarged vol. motor units in Ab Pol Brev; Abnormal EMG, acute/active denervation</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
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<td>---</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29**</td>
<td>81, f</td>
<td>0</td>
<td>No</td>
<td>5 years</td>
<td>8</td>
<td>0</td>
<td>15</td>
<td>Right</td>
<td>Retired</td>
<td>Sens. lat., Absent; Mot., 8.6 ms; Mild stroke after 2 months, R pain returned, after 8 f/u treatments, no reduction in pain</td>
</tr>
<tr>
<td>30*</td>
<td>83, f</td>
<td>x3, R</td>
<td>No</td>
<td>10 years</td>
<td>38</td>
<td>30</td>
<td>15</td>
<td>Right</td>
<td>Retired</td>
<td>+Tinel's; +Phalen's; Decr. Pinprick; Mild thenar flattening; Sens. Lat. “very prolonged”; Mot., 7.08 ms; cervical arthritis; Paget’s disease</td>
</tr>
<tr>
<td>31</td>
<td>84, f</td>
<td>x1, R</td>
<td>Yes, x2, R</td>
<td>7 years</td>
<td>49</td>
<td>0</td>
<td>11</td>
<td>Right</td>
<td>Retired</td>
<td>Required a few f/u treatments after 2 months</td>
</tr>
</tbody>
</table>

f/u, follow-up; TENS, transcutaneous electrical nerve stimulation; EMG, electromyography.

*Patient did not have satisfactory pain relief after laser acupuncture, microamps TENS and the other alternative therapies used in this study.

**Patient initially had pain relief. Two months posttreatment, after a mild stroke, pain returned; the follow-up treatments did not relieve the pain.

Sens. Lat. refers to median nerve sensory latency across the carpal tunnel; Mot. refers to median nerve motor latency across the carpal tunnel.
2 minutes, followed by a lower frequency of 9.25 Hz or 0.3 Hz for the next 18 minutes.

**Step 3. Laser applied to the fingers and hand.** While the TENS device was in place at the wrist, the red-beam laser was applied to other acupuncture points on the affected hand, for 3 minutes per point (approximately 1 J; or 4.6 J/cm² per point) (Fig. 1). These points included the following acupuncture points: Lung 11, Large Intestine 1, Pericardium 9, Triple Warmer 1, Heart 9, Small Intestine 1, distal BaXie points in the web spaces between the fingers, Triple Warmer 5, Large Intestine 4, Pericardium 8, Heart 7 and 8, and Lung 9 and 10. All points were treated at each treatment session. The acupuncturist often used 2–4 laser pointers at once, to treat 2–4 acupuncture points at once, in order to save time.

Additional secondary, alternative treatment modalities. Additional secondary, Oriental medicine therapies were used on an individual cases-by-case basis, including Chinese herbal medicine formulas, supplements, moxibustion, and stimulation of deeper acupuncture points on the posterior neck, shoulder, and elbow area with infrared-beam laser and/or needle acupuncture, as necessary. As is common practice in TCM, each patient was treated with an individually determined treatment protocol based on palpation, Pulse diagnosis, Tongue diagnosis, and patient history (Maciocia, 1994).

**Pulsed infrared laser treatments.** In most cases, additional deeper acupuncture points (especially points sensitive to palpation), were treated on the posterior neck area, shoulder (acupuncture point, Large Intestine 15) and elbow (acupuncture points Large Intestine 11 and 10), according to the acupuncture meridians that were involved, and distribution of possible radiating pain, using a pulsed, 10-W, 904-nm, infrared diode laser (Respond Laser model 2400, Respond Systems, Branford, CT), as explained above, within the real versus sham laser acupuncture treatment section. This laser emits six different pulse frequencies that range from 73 pps to 3500 pps. Usually, the high-frequency pulse rate was used first (3500 pps for 1 minute, 1.8 J/cm²), followed by lower pulse frequency rates for a few minutes (584 pps for...
TABLE 2. SUMMARY DATA FOR THREE SEPARATE AGE GROUPS, AND ALL CARPAL TUNNEL SYNDROME CASES (n = 31 CASES; 36 HANDS), BEFORE AND AFTER LASER ACUPUNCTURE, MICROAMPS TENS AND OTHER ALTERNATIVE THERAPIES

<table>
<thead>
<tr>
<th></th>
<th>Age enter study</th>
<th>Duration of pain prior to laser acupuncture</th>
<th>Mezack pain score before laser acupuncture</th>
<th>Change in Mezack pain score</th>
<th>Number of laser acupuncture treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>21 months</td>
<td>29.4</td>
<td>0</td>
<td>−29.4</td>
</tr>
<tr>
<td></td>
<td>S.D.</td>
<td>23.4</td>
<td>6.0</td>
<td>0</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>10</td>
<td>30.5</td>
<td>0</td>
<td>−30.5</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>3 to 72 months</td>
<td>16 to 36</td>
<td>0</td>
<td>−16 to −36</td>
</tr>
<tr>
<td>Age &lt;40 years</td>
<td>n = 8 hands</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>49.3 years</td>
<td>31.8</td>
<td>2</td>
<td>−29.8</td>
</tr>
<tr>
<td></td>
<td>S.D.</td>
<td>20.5</td>
<td>13.0</td>
<td>5.7</td>
<td>14.0</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>18</td>
<td>35</td>
<td>0</td>
<td>−31.5</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>2 to 60 months</td>
<td>2 to 47</td>
<td>0 to 20</td>
<td>−2 to −47</td>
</tr>
<tr>
<td>Age 40–60 years</td>
<td>n = 16 hands</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>75.8 years</td>
<td>34.3</td>
<td>8</td>
<td>−26.3</td>
</tr>
<tr>
<td></td>
<td>S.D.</td>
<td>57.7</td>
<td>12.9</td>
<td>11.4</td>
<td>16.7</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>48</td>
<td>35.5</td>
<td>1</td>
<td>−28.5</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>1 year to 18 years</td>
<td>8 to 51</td>
<td>0 to 30</td>
<td>0 to −51</td>
</tr>
<tr>
<td>All CTS cases</td>
<td>n = 36 hands</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>55.2 years</td>
<td>32.1</td>
<td>3.6</td>
<td>−28.5</td>
</tr>
<tr>
<td></td>
<td>S.D.</td>
<td>41.8</td>
<td>11.6</td>
<td>8.1</td>
<td>13.5</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>24</td>
<td>32.5</td>
<td>0</td>
<td>−29</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>2 months to 18 years</td>
<td>2 to 51</td>
<td>0 to 30</td>
<td>0 to −51</td>
</tr>
</tbody>
</table>

TENS, transcutaneous electrical nerve stimulation; CTS, carpal tunnel syndrome.

1 minute, 0.3 J/cm²; and 73 pps for 1 minute, 0.04 J/cm². Treatment times varied from case to case depending on the type and location of pain. If the patient had a TCM diagnosis of Deficient Qi and Deficient Blood, the 3500 pps rate was not always used, and more time was used with the lower frequencies, especially the 584 pps rate. The patient felt nothing from the infrared laser.

Needle and moxibustion acupuncture treatments. In some patients, the deeper acupuncture points on the posterior neck, shoulder, and elbow areas (especially points sensitive to palpation), were also treated with standard acupuncture needles; or with small intradermal needles (3–6 mm in length) that were sometimes taped in place for a few days. Additional body acupuncture points were stimulated with standard needle acupuncture, as necessary, on a case-by-case basis, according to TCM diagnosis. Wolfe (1995) has summarized common TCM diagnoses and treatments for CTS, including standard acupuncture needle, moxibustion and Chinese herbal therapies. These common TCM diagnoses were also observed among the cases treated in the present study. For example, in case 19, where cold hands were a major problem for the patient (an ice cream server, with 6-month duration of pain), the TCM diagnosis of Cold Obstruction was made, and additional treatment with moxibustion was performed on the hand (superficial heating of acupuncture points with the herb, Artemisia vulgaris).

Chinese Herbal Medicine Formulas. In addition, some patients used Chinese herbal medicine formulas in pill form, on an individual case-by-case basis, according to TCM diagnosis, as directed by the acupuncturist. The most common TCM diagnosis requiring Chinese herbal therapy was the diagnosis of Deficient Qi and Deficient Blood (often Deficient Kidney
Essence). These patients were given the formula, Astra Essence, in pill form (Health Concerns, Oakland, CA).

Supplements. In most cases, the dietary supplement, omega-3 fish oil capsules, was also used, according to the protocol of Omura (Omura et al., 1992; Omura, 1994). Omura et al. (1992) has observed with bi-digital O-ring, resonance testing that many chronic pain patients present with a subclinical, viral infection in the area of pain; it is often herpes simplex type I virus on one side of the body, and type II, on the opposite side. None of the patients who participated in this clinical outcome study were examined by Dr. Omura, therefore it is not known if any of them had a subclinical, viral condition in the median nerve area, at the wrist. Patients were offered the option of trying the Omura treatment protocol with omega-3 fish oil capsules. Most patients used this for the duration of the treatments (4–5 weeks), in addition to the other treatments administered.

There were no negative side effects or untoward events observed with any aspects of this alternative treatment program.

3The omega-3 fish oil capsules (SDV, Boca Raton, FL or M.I.C. International, Jersey City, NJ) were used. Three times a day, the patient took one capsule with water, on an empty stomach, followed by 30 seconds of massage at the “wrist representation area” on the fingers (distal interphalangeal joint on the index and ring fingers), in order to promote vasodilation to the “wrist target organ.” These “wrist representation areas” on the distal finger joints are an adaptation of the Korean Hand Acupuncture System (Yoo, 1988, p. 239, p. 245). The purpose of massage at the target “representation” areas (distal finger joints) was to increase vasodilation at the target sites (wrist areas), thus promoting increased blood flow with the supplements or herbs, to that target area. It would be too painful to massage the wrist area, directly. No endorsements of omega-3 fish oil, or medical claims are suggested for this experimental protocol.
RESULTS

Data for the 31 patients were examined according to age at entry (Table 2 and Fig. 2). There were three age groups: (1) less than 40 years (7 cases, 8 hands); (2) 40–60 years (12 cases, 16 hands); (3) older than 60 years (12 cases, 12 hands). A two-way, mixed-design analysis of variance (ANOVA) was performed with age as the between-subjects factor, and the Melzack pain scores (pretreatment and posttreatment) as the repeated measure. There was a significant main effect for change in the Melzack pain scores $F(1,33) = 154.27$, $p < .0001$; no significant main effect for age $F(2,33) = 2.18$, $p = .13$, and no significant interaction between age and change in pain scores $F(2,33) = 0.242$, $p = .79$.

Duration of pain

The three age groups differed in duration of pain prior to entry into the study. $F(2,33) = 5.07$, $p = .012$. Post hoc analysis with Scheffe test showed that group 3 (>60 years) had a significantly longer duration of pain than group 1 ($p = .047$) and group 2 ($p = .026$) (Table 2).

Number of treatments

The three age groups differed in the number of treatments $F(2,33) = 3.31$, $p = .049$. Post hoc analysis with Scheffe test showed there was a borderline significant difference between the number of treatments between group 3 and group 1 ($p = .052$). This difference is mainly due to an outlier in group 1, who only required five treatments (case 1) (Table 1).

Overall, for the 36 hands, analysis of variance with one repeated measure (pretreatment and posttreatment Melzack pain scores) showed that posttreatment, the pain scores were significantly reduced $F(1,35) = 161.25$, $p < .0001$, with a mean pain score reduction of $-28.5$ points (SD, 13.5). Pretreatment, the mean pain score was 32.1 (SD, 11.6); Posttreatment, 3.6 (SD, 8.1) (Table 2). In summary, 28 of 31 patients (90.3) reported reduced pain after these treatments, at a level of either no pain, or pain reduced by more than 50% (33/36 hands, 91.6%). All 12 cases (14 hands) who had previously failed with surgical release, obtained pain relief after this alternative treatment program (cases 3, 6, 8, 9, 10, 12, 14, 18, 22, 23, 25, 31). This included two patients who had failed two surgical release procedures on the same hand (cases 9, 31) (Table 1).

Age group less than 40 years

Posttreatment, 7 of 7 cases (8/8 hands, 100%) attained pain scores of 0, and all cases either continued to work during treatment or returned to work. There was one workmen’s compensation case (case 1), a secretary who was able to return to work after treatment. She had a short duration of pain (3 months) and required only five treatments. Two of eight hands had failed with cortisone injections (cases 3, 4); two of eight hands had failed with surgical release (cases 3, 6); all were successfully treated.

In follow-up at 1–2 years, only 1 of 7 cases (1/8 hands, 12.5%) required additional treatments (case 3, female maintenance worker; after 4–5 months, nine treatments) (Table 1). Thus, pain control had remained stable in 7 of 8 hands (87.5%) after 1–2 years in the less than 40 age group, without follow-up treatment.

Age group 40–60 years

Posttreatment, 11 of 12 cases (15/16 hands, 93.7%) attained pain scores of 0 (14 hands), or reduced pain by more than 50% (1 hand). There were three workmen’s compensation cases: 1 returned to work full-time (case 17, factory worker in packaging/wrapping) and 2 cases returned to work part-time (cases 8 and 10, computer operators in the same office; both with posttreatment pain scores of 0, but who requested only part-time work status). Eight other cases who were already working at time of entry into treatment continued to work. Only case 16 (housewife) was not employed outside the home.

The single case in this 40–60 age group who failed to obtain pain relief (case 11, age 47, computer operator and weight lifter) continued to abuse his hands throughout treatment, performing heavy weight lifting daily. After this
alternative therapy program, this patient underwent cortisone injection. He continued to lift weights and obtained no long-term benefit from this latter treatment.

Eight of 16 hands in this group had failed with cortisone injections (cases 8, 9R&L, 10, 14R&L, 17, 18), and 8 of 16 hands had failed with surgery (cases 8, 9R&L, 10, 12R&L, 14, 18); all of these cases achieved satisfactory pain relief after this alternative therapy program. Their posttreatment pain scores were all 0, except case 18, who had a posttreatment pain score of 12 (pretreatment, 41).

Summary: first two age groups

Across the first two age groups (<40 years, and 40–60 years) where most cases were employed (ages 24–56 years), 18 of 19 cases (23/24 hands, 95.8%) were successfully treated with this alternative therapy program. Among these 18 cases successfully treated, only 2 cases required follow-up treatments within the first year (2/23 hands, 8.7%). Ten of the 24 hands in these first two age groups had failed with cortisone injections, and 10 had failed with surgery; all of these hands obtained satisfactory pain relief. Pain control remained stable after 1–2 years without any follow-up treatments in 21 of 23 hands (91.3%). All employed cases (n = 18) remained employed in professions including secretary, repair service, maintenance worker, autobody mechanic, teacher, computer operator, nurse’s aid, artist/painter, nail technician, photographer, factory worker, and ice cream server.

Age group older than 60 years

Posttreatment, 10 of 12 cases (10/12 hands, 83.3%) attained pain scores of 0 (n = 6) or pain reduction of more than 50% (n = 4). All cases were retired. Seven of 12 hands (58.3%) had failed with cortisone injection (cases 20, 21, 22, 23, 25, 30, 31); and 6 of 7 of these cases obtained pain relief after this alternative therapy program (all except case 30). Four of the 12 hands (33.3%) had failed surgery (cases 22, 23, 25, 31); and 4 of 4 of these cases obtained pain relief following this alternative therapy program (Table 1).

In follow-up at 1–2 years, among the 10 hands successfully treated, 3 hands had return of pain for no known reason, at 1–3 months posttreatment, requiring 6–8 additional treatments (cases 21, 26, 31), again with good resolution of pain. Two other cases also had return of pain for no known reason, however, each case had a new major medical problem. Case 25, age 76, required additional treatment 6 months later, at 2 months postcoronary bypass surgery; his pain score again returned to 0. Case 29, age 81, required additional treatment 2 months later, after a mild stroke; however, after 8 treatments there was no reduction in hand pain. Thus, the long-term outcome in this CTS case with stroke was similar to that for the stroke case in Footnote 1. Both cases had central nervous system involvement plus peripheral nervous system involvement, and both cases had no long-term CTS pain relief.

In summary, in this oldest age group, pain control was less stable within the first year, where 5 of 10 cases (50%) required follow-up treatments. In 4 of 5 of these cases (80%), satisfactory pain relief was again achieved.

Nerve conduction studies

As mentioned above, under Subjects, data from NCS and EMG were available for only 6 cases in this clinical outcome report, all in the oldest age group (Table 1). There were two mild CTS cases (case 22, with 3.75 ms, motor DL; sensory latency, 3.65 ms; and case 23, with 4.3 ms, motor DL; sensory latency, absent), and one moderate CTS case (case 20, with 5.3 ms, motor DL; sensory latency not reported); all had good pain relief after this alternative therapy program. There were, however, 3 severe CTS cases (case 28, with abnormal EMG; case 29, with 8.6 ms, motor DL; and case 30, with 7.08 ms, motor DL). Two of these three severe CTS cases did not have satisfactory pain reduction after 15 treatments. The third severe CTS case (case 29, age 81, with 8.6 ms, motor DL) had initially good pain relief after 15 treatments, however, after a mild stroke at 2 months after the last treatment, her pain returned and it was not alleviated after 8 follow-up treatments. In summary, 3 of 3 severe CTS cases did not have satisfactory pain relief.

In summary, NCS data may be predictive of good versus poor response to this alternative
therapy program. Results from the present study, as well as those from the ongoing controlled research (Naeser et al., 1996, Naeser, 1997a) suggest that good pain reduction is likely with low-level laser and microamps TENS if the motor latency is less than 7.0 ms (sensory latency may be absent). No pain reduction is likely to occur, however, if the motor latency is more than 7.0 ms or denervation is present on EMG. More cases should be studied with electrodiagnostic testing.

DISCUSSION

Overall, 28 of 31 cases (90.3%) and 33 of 36 hands (91.6%) treated with this alternative therapy program obtained successful pain relief in 4–5 weeks. This significant pain reduction (p < .0001) was observed across all three age groups. Among those employed at the time of treatment (ages 24–56 years), 21 of 23 hands (91.3%) maintained stable pain relief over the next 1–2 years. The two hands that required follow-up treatments within the first year were again successfully treated within a few weeks.

Overall, results from this study are compatible with results from two other low-level laser studies with CTS. In the uncontrolled study by Wong et al. (1995), an overall success rate of 91.4% (32/35) was observed with infrared laser (830 nm, 100 mW) stimulation at the upper back and posterior neck (12–30 J per point) in office workers. In the uncontrolled study of Weintraub (1997), an overall success rate of 77% (23/30) was observed with infrared laser (830 nm, 30 mW) stimulation on the wrist/hand at 5 points (9 J per point). The high success rate in the present study (91.6%) is nearly identical to the results observed in the Wong et al. (1995) study (91.4%). These two studies shared the common feature that infrared laser was used on the posterior neck and upper back, thus suggesting that future studies using low-level laser with CTS cases should not only treat the wrist/hand, but also the upper back and cervical neck area where the nerve roots emerge. No negative side effects were reported in any studies. The present study is the only one to report follow-up status at 1–2 years.

Patients who continue to smoke do not have good success with this treatment, and cases who have had persistent numbness in the fingertips (24 hours a day for longer than 18 months) do not obtain good relief from the numbness, although there is usually a reduction in pain (Naeser et al., 1997). Cases with only intermittent numbness usually obtain relief from the numbness, as well as pain.

Most patients who obtain pain relief with this alternative therapy program begin to report a noticeable reduction in pain after nine treatments. This nine-treatment mark is compatible with results from Walker (1983), where after 10 red-beam laser treatments, a sharp increase was observed in the serotonin byproduct, 5-hydroxyindoleacetic acid, in the urine of 19 of 26 chronic pain cases who ultimately obtained good pain relief after 30 red-beam laser treatments. The urine levels returned to baseline after 20 treatments. We have observed that patients should be given two treatments beyond their report of no pain, otherwise the pain may return. It is recommended that cases receive at least 15 treatments.

The primary treatment modalities used in all cases was red-beam, low-level laser acupuncture and microamps TENS on the hand. The exact mechanisms involved with pain relief after treatment with these modalities are unknown. Some possibilities may include the following: (1) local increase in ATP on the cellular level near the median nerve at the wrist (Passarella, 1989, 1983, 1984, 1987, 1988; Cheng et al., 1982); (2) decrease in inflammation in the area (Goldman et al., 1980; Palmgren et al., 1989); and (3) temporary increase in serotonin levels (Walker, 1983).

Weintraub (1997, p. 1031) has proposed the following mechanisms to be involved with effective neurolysis in CTS cases after low-level laser therapy. “It is tempting to speculate that laser light alters biological mechanisms and induces depolarization with secondary repolarization and indirect anti-inflammatory effects. Whatever the biological mechanism, one cannot exclude effects on nonneural tissue, ie, volar carpal ligament, tenosynovium, blood vessels, etc. Because the anatomy remains the same, the postulated and presumed raised intracarpal pressure is reduced directly or indirectly and would be consistent with the experimental benefit from laser light.”
In cases where low-level laser therapy failed in the Weintraub (1997) study, e.g., prolongation of distal latency greater than 5.0 ms in CMAP (5/7 cases), and sensory nerve action potential (SNAP) greater than 4.3 ms (3/7 cases), as well as absent SNAP, there may have been severe compression inducing ischemia and reduction of epineural blood flow. "This process ultimately is responsible for capillary stasis, hypoxic injury, and epineural edema followed by axonal loss" (Lundberg et al., 1983; Sunderland, 1976; Weintraub, 1997, p. 1031). Thus, the 5 of 7 cases who failed to respond to low-level laser therapy in the Weintraub study had motor DL greater than 5.0 ms; or sensory latency greater than 4.3 ms (or absent). In the present study, where multiple alternative therapy modalities were used in addition to low-level laser, one case was successfully treated who had motor DL greater than 5.0 ms (case 20, with motor DL, 5.3 ms). Three cases who failed to respond to the alternative therapies in the present study, each had motor DL greater than 7 ms (case 30, 7.08 ms; case 29, 8.6 ms) or evidence of axonal damage on EMG (case 28).

Results from each study support the notion that NCS and EMG data are helpful in understanding which cases are most likely to improve after a series of treatments including low-level laser, and/or other alternative therapy modalities. Thus far, it appears that CTS cases with a motor DL of less than 7 ms and no abnormality on EMGg are likely to have good response with the alternative, multimodality therapy program used in the present clinical outcome report. More cases with electrodiagnostic data are likely to provide refined criteria for candidacy for this alternative therapy program for CTS.

Additional mechanisms associated with acupuncture treatments for pain

Another mechanism that might underlie successful treatment of pain after acupuncture is increased blood flow to the brain, especially the thalamus. The Hospital of the University of Pennsylvania has recently completed a brain single-photon emission computed tomography (SPECT) blood flow study with a variety of chronic pain cases who obtained a reduction in pain after a series of acupuncture treatments (Alavi et al., 1996, 1997a, 1997b). A baseline brain SPECT scan was performed before an acupuncture treatment, and immediately after the treatment. Pre-acupuncture (when pain was present), there was asymmetric, lower blood flow to the thalamus; post-acupuncture (when pain was no longer present), there was normalization of blood flow to the thalamus, in most cases.

A brain SPECT study with chronic stroke patients before and after an acupuncture treatment is currently in progress in the neuroimaging laboratory of the second author (M.N.) at the D.V.A. Medical Centers, Boston and West Roxbury, Massachusetts. Brain blood flow is measured before and immediately after one acupuncture treatment on the same day. Needle and electroacupuncture, and laser acupuncture with red-beam laser on the hand and infrared laser on the posterior neck are used. Four of five stroke cases showed an increase in blood flow to the thalamus (especially ipsilateral to the paralysis, contralateral to the lesion) after the acupuncture treatment, ranging from +3% to +24% (Naeser, 1997a). The latter increase of +24% was observed in a patient who had already had 3 years of red-beam laser acupuncture treatments on the hand at home, whereas for the other cases, this was their first acupuncture treatment. The Alavi et al. studies (1996; 1997a; 1997b) had observed a change of approximately +23% in blood flow postacupuncture in the thalamus in 4 of 5 pain patients who had had a series of acupuncture treatments. Thus, it is to be expected that most CTS pain cases successfully treated in the present clinical outcome study required a series of 12-15 treatments before stable pain relief was obtained. In summary, it is possible that the stimulation of acupuncture points with low-level laser in the present study with chronic pain patients also promoted increased blood flow to parts of the brain, especially the thalamus. More research with brain imaging pre- and post-needle and/or laser acupuncture is needed.

Potential cost savings

There are potential cost savings for treatment of CTS with this alternative therapy program,
### Table 3. Potential Cost Savings with Laser Acupuncture, Microamps TENS and Other Alternative Therapies to Treat Carpal Tunnel Syndrome*

<table>
<thead>
<tr>
<th>Cost to treat</th>
<th>Cost to treat</th>
</tr>
</thead>
<tbody>
<tr>
<td>one case,</td>
<td>1 million cases,</td>
</tr>
<tr>
<td>carpal tunnel syndrome</td>
<td>carpal tunnel syndrome</td>
</tr>
<tr>
<td>Current cost without surgery</td>
<td>$5,246</td>
</tr>
<tr>
<td>Current cost with surgery</td>
<td>$20,925</td>
</tr>
<tr>
<td>Current treatments average cost</td>
<td>$12,000</td>
</tr>
<tr>
<td>Cost with laser Acupuncture, microamps TENS and other alternative therapies @ $60 per treatment</td>
<td>15 Office visits</td>
</tr>
<tr>
<td>Office visits</td>
<td>$900</td>
</tr>
<tr>
<td>Cost with laser acupuncture, microamps TENS and other alternative therapies</td>
<td>5 mW laser pointer</td>
</tr>
<tr>
<td></td>
<td>MicroStim 100 TENS</td>
</tr>
<tr>
<td></td>
<td>1 Office visit for training</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Home treatment</td>
<td>$1,097</td>
</tr>
<tr>
<td>Average cost with laser acupuncture, microamps TENS and other alternative therapies</td>
<td>$1,000</td>
</tr>
<tr>
<td>Average cost savings with laser acupuncture, microamps TENS and other alternative therapies vs. current average cost</td>
<td>$11,000</td>
</tr>
</tbody>
</table>

*Current cost estimates are based on Clairmont (1997). TENS, transcutaneous electrical nerve stimulation.

Even if only half the total estimated number of 2 million cases are treated with it (Table 3). (The cost for the Chinese herbal medicine formulas and the omega-3 fish oil capsules used for 4–5 weeks is less than $50). The treatments may be performed either in the office of a licensed acupuncturist trained in laser acupuncture; or with early-stage, mild cases, by the patient in a supplemental home treatment program under supervision of the acupuncturist (Naeser et al., 1996, 1997).  

In the present study with 31 cases (36 hands), 16 surgical procedures had been performed on 14 hands. The estimated cost to manage one CTS case with surgery and rehabilitation in the United States is about $20,000 (Clairmont, 1997). Thus, 16 surgeries at $20,000 reflects an estimated cost of $320,000 for surgical management of these 14 cases. These 14 cases obtained successful pain relief after this alternative treatment program (average cost per case, $1,000) (Table 3). Thus, the total cost with this treatment program for these 14 cases was $14,000. The potential cost savings that could have been realized for these 14 hands, if they had been treated with this program earlier (instead of 1–2 surgical procedures), is $306,000.

The results in the present clinical outcome report are likely a combination of both the primary and secondary treatment modalities offered to the patients in this clinical study. The relative contribution of either the primary treatment modalities (red-beam laser acupuncture and microamps TENS on the affected hand), versus the secondary treatment modalities cannot be determined. There is, however, probably a synergistic effect, from the various modalities used (acupuncture plus herbal). The combination of acupuncture plus herbal therapies has, for example, been at the traditional center of Oriental medicine for centuries (Maciocia, 1994). It would be of academic interest to learn more about the relative contribution of each of the secondary treatment modalities used in this clinical outcome study with CTS cases; and while important, the research cost in terms

*The first two CTS cases (mild CTS) treated by M.N. with laser acupuncture and microamps TENS used home treatments, only. Both have had no recurrence at 8 years follow-up, and both remain employed and are able to perform keyboard/computer work. Each case did require a few weeks of follow-up treatments at the end of the first year.
of both time and expense to examine the effect of each secondary modality alone, and in combination, would likely be high (Abelson, 1990; Naeser, 1997b).

Future clinical studies with this alternative treatment program including primarily, red-beam laser acupuncture and microamps TENS on the affected hand, plus secondarily, other alternative modalities used on a case-by-case basis, appear warranted. Additional studies should better define when the best time would be to intervene with this form of treatment (eg, probably during the early conservative management phase), and in which level of electrodiagnostic severity (eg, the sensory latency may be absent, but the motor latency should be less than 7.0 ms on NCS, and no evidence of denervation on EMG). This alternative treatment has potential to help 90% of younger and middle-age workers in the early, mild/moderate stage of CTS, thus helping to prevent severe CTS, and later need for surgery.

Sources for additional information

The American Association of Oriental Medicine in Catasauqua, Pennsylvania, maintains a registry of licensed acupuncturists in the United States who have been trained in laser acupuncture (610) 266-1433.

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