

# Laser Therapy: A Randomized, Controlled Trial of the Effects of Low Intensity Nd:YAG Laser Irradiation on Lateral Epicondylitis

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**ABSTRACT.** Basford JR, Sheffield CG, Cieslak KR. Laser therapy: a randomized, controlled trial of the effects of low intensity Nd:YAG laser irradiation on lateral epicondylitis. *Arch Phys Med Rehabil* 2000;81:1504-10.

**Objective:** To assess the effectiveness of low intensity laser therapy in the treatment of lateral epicondylitis.

**Design:** A double-masked, placebo-controlled, randomized clinical trial.

**Setting:** A physical medicine and rehabilitation clinic.

**Participants:** Fifty-two ambulatory men and women (age range, 18–70yr) with symptomatic lateral epicondylitis of more than 30 days in duration and a normal neurologic examination.

**Intervention:** Subjects were bloc randomized into 2 groups with a computer-generated schedule. All underwent irradiation for 60 seconds at 7 points along the symptomatic forearm 3 times weekly for 4 weeks by a masked therapist. The sole difference between the groups was that the probe of a 1.06- $\mu\text{m}$  continuous wave laser emitted 204mW/cm<sup>2</sup> (12.24J/cm<sup>2</sup>) for the treated subjects and was inactive for the control subjects. Subjects were assessed at the beginning, midpoint (session 6), and end (session 12) of treatment, as well as at follow-up 28 to 35 days after their last treatment.

**Main Outcome Measures:** Pain in last 24 hours, tenderness to palpation, and patient's perception of change (benefit).

**Results:** The treated and untreated groups were well matched demographically. Masking was maintained for subjects and therapists; however, the groups did not vary to a statistically significant extent in terms of the main outcome measures either during treatment or at follow-up. Secondary outcome variables, such as grasp and pinch strength, medication use, and pain with grasp and pinch, also failed to statistically differ significantly between the groups. No significant treatment side effects were noted.

**Conclusion:** Treatment with low intensity 1.06- $\mu\text{m}$  laser irradiation within the parameters of this study was a safe but ineffective treatment of lateral epicondylitis. Further research seems warranted in this controversial area.

**Key Words:** Lasers; Epicondylitis, lateral humeral; Rehabilitation.

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**L**ASER THERAPY is a widespread but controversial treatment based on the belief that laser radiation, at intensities too low to produce significant heating, produces clinically meaningful improvements in a variety of soft tissue conditions, such as soft tissue injuries, wounds, and neuropathies.<sup>1</sup> At first blush, the idea that light has inherent "curative" properties in the absence of tissue heating seems strange and intuitively false. Nevertheless, the concept is neither new nor unique. For example, sunlight was a therapeutic agent in ancient Greece, and in the 1890s, the destructive effects of ultraviolet radiation were used to treat cutaneous tuberculosis.<sup>2</sup> Today, the electromagnetic spectrum is well established in medicine: short wave diathermy is a common physical therapy treatment,<sup>3,4</sup> and ultraviolet and visible light are used as bactericidal agents, as well as in the treatment of psoriasis and mood disorders.<sup>1</sup>

Initial work with this therapy began in eastern Europe more than 30 years ago.<sup>5</sup> These studies were poorly controlled but intriguing because they found that low power ( $\leq 1\text{mW}$ ) laser irradiation, as well as some wavelengths of monochromatic light, altered hair growth, bacterial processes, and accelerated wound healing<sup>6-8</sup> in a way that was independent of heating.<sup>1,7,9-12</sup> These first communications were often incomplete and difficult to assess. Nevertheless, their claims of success and their emphasis on the nonthermal nature of the treatment caught the attention of other investigators. With time, interest has grown, research rigor has improved, and clinical use has spread.<sup>1</sup> Today, low intensity lasers (also known as low energy or low power lasers) are used in as many as 30% to 40% of physical therapy, dental, and sports clinics in some parts of Europe and Asia.<sup>1,13</sup> Treatment appears safe,<sup>1,13</sup> and although this therapy has not received Food and Drug Administration approval for clinical use, interest in the United States is growing.<sup>1</sup>

As is true for any new and controversial therapy, treatment parameters and the mechanism of action are important and contentious issues. Early laser therapy researchers emphasized the importance of a variety of light and electromagnetic characteristics, such as polarization, coherence, pulse rate, and wavelength. Although there is still some interest in many of these quantities, the degrading influence of tissue scattering on polarization and coherence, as well as reports that monochromatic light itself has stimulating abilities, has focused interest on the importance of wavelength.<sup>1</sup> As a result, although early researchers used an eclectic array of visible and infrared (IR) devices, clinical treatment and research today almost always use either visible red (about 630 $\mu\text{m}$ ) or IR lasers and diodes with wavelengths ranging between .78 and 1.06 $\mu\text{m}$ . The early lasers were primitive, and aperture sizes were quite small. With time, aperture size has grown, but treatment intensities (a few hundred mW/cm<sup>2</sup>) have tended to remain the same or grow modestly.<sup>1,13</sup> Conversely, treatment dosages, although staying at about 1 to 4J/cm<sup>2</sup> for wound treatment, are now often significantly higher (eg, 10–15+J/cm<sup>2</sup>) for deeper musculoskeletal conditions.

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The mechanism of low intensity laser therapy is controversial and only partially understood. However, some things are known. For example, alterations in cellular function occur in the absence of significant heating (ie, temperature changes  $\leq 0.5^\circ\text{C}$ ) in cells and bacteria after irradiation at specific wavelengths.<sup>1,10,11,14,15</sup> In addition, spectroscopic studies find radiation absorption peaks attributed to components of the mitochondrial respiratory chain correspond with the wavelengths that produce changes in cellular behavior.<sup>1,10-12</sup> The very low energies involved in this approach should be kept in mind. As a reference point, the energies, powers, and power intensities involved in laser therapy are 10 to 100 times less than those involved in therapeutic short wave or ultrasound<sup>4</sup> and only a thousandth of those used by surgical lasers.<sup>8</sup>

This background whetted our interest, so we chose to study systematically the potential benefits of this novel and controversial therapy. Because laser therapy is often promoted for the treatment of soft tissue musculoskeletal dysfunction,<sup>1,13</sup> we decided to investigate its effectiveness in 2 representative complaints. The first was musculoskeletal low back pain, and our hypotheses was that treatment would result in lessened pain, enhanced level of function, and improved lumbar mobility. We completed this first study and, as reported in the June 1999 *Archives*,<sup>16</sup> found that irradiation produced modest, but statistically significant, improvements in pain and functional level without improving lumbar mobility.

This present study is a continuation of our musculoskeletal investigations. We extended our interest to another common and refractory soft tissue condition. Specifically, we performed a double-masked, randomized, placebo-controlled clinical evaluation of the efficacy of a 1.06- $\mu\text{m}$  (IR) neodymium:yttrium-aluminum-garnet (Nd:YAG) continuous wave (CW) laser<sup>a</sup> in the treatment of lateral epicondylitis. Our hypothesis was that irradiation would lessen pain, reduce tenderness, and improve function.

## METHODS

This protocol was reviewed and approved by the institutional review board of our institution. After approval, 62 otherwise healthy individuals with lateral epicondylitis of more than 30 days' duration were recruited with announcements in our in-

stitutional newsletter and on referral from local physicians and chiropractors. Men and women between the ages of 18 and 70 years were accepted for entry, but, although we know of no established risk in pregnancy, women were required to be postmenopausal or practicing an effective means of birth control (pregnancy tests were obtained in those with childbearing potential). Subjects were not accepted for the study if litigation or workman's compensation issues were pending. Previous treatment, with the exception of surgery, did not preclude participation if there had been no treatment of this problem by a physician, physical therapist, chiropractor, or other health care provider within the previous 30 days. Individuals administered corticosteroids for any reason within the last 30 days were also excluded. Analgesic and nonsteroidal anti-inflammatory medication use was not encouraged, but was monitored as an experimental variable.

Diagnosis of lateral epicondylitis was made by a physician experienced in musculoskeletal diseases and depended on a normal neurologic examination (ie, normal appreciation of light touch and sharpness, symmetric upper extremity deep tendon reflexes [biceps, triceps, brachioradialis], normal upper extremity muscle strength), as well as complaints of localized pain and tenderness in the proximal lateral forearm and epicondyle. Physical examination also assessed tenderness to palpation and quantitative (strain gauge) grasp and pinch strength. Pain with grasp and pinch, as well as pain and strength (scored on a 5-point scale) with manually resisted wrist and second finger extension, were also measured. Subjects were excluded if they described radicular pain or if they noted changes in upper extremity strength not attributable to lateral epicondylitis related pain. Subjects were also instructed to fill out a pain diagram.

After a successful examination and history, the most symptomatic forearm was selected for treatment, and the participants were bloc randomized by 2s with a computer generated schedule into 2 groups (A, B) over a period extending from November 21, 1997, to August 23, 1999. All subjects were instructed in conservative treatment options (ie, ice massage, cross-fiber friction massage, wrist extensor stretching) and familiarized in an identical manner with the study by a masked therapist. Seven physical therapists were trained to use the laser. Treat-

Table 1: Group Demographics

Subject Characteristics	Active Group (n = 23)	Control Group (n = 24)	p
Sedentary (%)	22/23 (96)	21/24 (87)	.609*
Female (%)	13/23 (57)	15/24 (63)	.770*
Age (yr)	45.1(45.0)	45.6 (47)	.685 <sup>†</sup>
Symptom duration (mo)	5.7(4.0)	7.1 (5.0)	.428 <sup>†</sup>
Symptom duration 1 to $\leq 4$ mo	13/23	11/24	
Symptom duration > 4mo	10/23 (4.0)	13/24	
Orthotic use			
Currently use orthotic	11/23 (48)	12/24 (50)	1*
Past use of orthotics	12/23 (52)	18/24 (75)	.135*
Pain with grasping (%)	20/23 (87)	18/24 (75)	.461*
Previous treatment with physical therapy, injection, or chiropractic	6/23 (26)	11/24 (46)	.227*
Analgesic use (NSAID) (no./d)	2.2 (1.0)	3.1 (3.0)	.097 <sup>†</sup>
Analgesic use (acetaminophen) (no./d)	1.6 (1.0)	1.6 (1.0)	.841 <sup>†</sup>
Right extremity treated (%)	17/23 (74)	19/24 (79)	.740*

Abbreviations: NSAID, nonsteroidal anti-inflammatory drug.

\* Chi-square test.

<sup>†</sup> Wilcoxon's rank sum test (mean given).

Table 2: Signs and Symptoms at Initial Evaluation

	Active Group	Control Group	p*
Main outcome variables			
Maximal pain in last 24hr <sup>†</sup>	47.7 (45)	42.1 (33.8)	.530
Maximal tenderness on palpation <sup>†</sup>	66.3 (68.0)	65.6 (65.8)	.807
Secondary outcome variables			
Grip strength (kg) <sup>‡</sup>	27.7 ± 25.3	32.4 ± 32.6	.235
Pinch strength (kg) <sup>‡</sup>	5.2 ± 4.6	4.9 ± 4.0	.675
Pain with grasp <sup>†</sup>	61.1 (67.5)	56.6 (61.3)	.558
Pain with pinch <sup>†</sup>	55.7 (59.8)	42.7 (36.0)	.159

\* Wilcoxon's rank sum test (mean given).

<sup>†</sup> Visual analog scale (mm) (mean given). A lower value is equivalent to less pain or tenderness.

<sup>‡</sup> Values presented as mean ± SD.

ment was performed in a standard masked manner by a therapist from this trained pool placing a toggle switch on the back of the laser in either an A or B position. The subjects then entered the treatment room and rolled up the sleeve (as necessary) of their designated forearm. Therapist and subjects wore protective goggles during treatment. Participants were irradiated for 60 seconds at 7 sites along the forearm (3 contiguous sites immediately above, at, below the lateral epicondyle, as well as at the distal wrist extensor tendons, the volar wrist, 2 contiguous sites on the medial epicondyle) on a 3-times weekly, 4-week schedule. Irradiation was performed with a 1.06- $\mu\text{m}$  Nd:YAG CW laser<sup>a</sup> with a 5-cm diameter applicator. The only treatment difference between the 2 groups was that 1 was irradiated with the probe emitting an average intensity of 204mW/cm<sup>2</sup> (12.24J/cm<sup>2</sup>/treatment) and the other was "irradiated" with the same, but inactive, probe. Subjects were allowed to make up a maximum of 2 missed treatments (on days they were not scheduled for treatment) over the course of the experiment and received a \$20 remuneration fee if they completed at least 11 sessions and returned for a follow-up visit. Subjects were evaluated before the 1st, 6th, and 12th sessions of treatment, as well as at 1-month follow-up (28–35d after the last session). Each evaluation was administered by an experienced and masked physician or therapist (JRB, CGS) not involved in the treatment who knew only the subjects' group assignment. Each evaluation consisted of a repetition of the questions and examination given when entering the study.

Table 3: Signs and Symptoms at Midpoint Evaluation

	Active Group	Control Group	p*
Main outcome variables			
Pain level in last 24hr <sup>†</sup>	43.1 (37)	39.2 (40)	.551
Maximal tenderness on palpation <sup>†</sup>	58.4 (55.0)	53.1 (56.3)	.516
Overall change <sup>†</sup>	62.4 (65.0)	69.0 (70.3)	.268
Secondary outcome variables			
Grip strength (kg) <sup>‡</sup>	30.7 ± 31.5	33.3 ± 30.9	.812
Pinch strength (kg) <sup>‡</sup>	5.9 ± 4.5	5.2 ± 4.5	.310
Pain with pinch <sup>†</sup>	56.8 (53.5)	48.6 (54)	.431
Pain with grasp <sup>†</sup>	46.6 (37.0)	41.9 (51.5)	.811

\* Wilcoxon's rank sum test (mean given).

<sup>†</sup> Visual analog scale (mm) (mean given). A lower value is equivalent to less pain or tenderness.

<sup>‡</sup> Values presented as mean ± SD.

Table 4: Signs and Symptoms at Last Treatment

	Active Group	Control Group	p*
Main outcome variables			
Pain level in last 24hr <sup>†</sup>	34.3 (28.0)	25.1 (21.0)	.371
Maximal tenderness on palpation <sup>†</sup>	40.8 (33.5)	41.6 (42.3)	.758
Overall change	72.1 (76.5)	76.9 (83)	.350
Secondary outcome variables			
Grip strength (kg) <sup>‡</sup>	32.1 ± 33.6	34.5 ± 37.0	.601
Pinch strength (kg) <sup>‡</sup>	5.8 ± 5.0	5.0 ± 4.8	.276
Pain with grasp <sup>†</sup>	41.6 (39)	33.3 (26.3)	.413
Pain with pinch <sup>†</sup>	42.1 (28.8)	29.6 (26.5)	.301

\* Wilcoxon's rank sum test (mean given).

<sup>†</sup> Visual analog scale (mm) (mean given). A lower value is equivalent to less pain or tenderness.

<sup>‡</sup> Values presented as mean ± SD.

Subjects were queried about the main outcome variables, changes in activity levels and medication use, and their perception of change, the nature of their pain (location, intensity, precipitating factors), and whether they had noted adverse treatment effects. Maximal grasp was assessed by having the subjects exert a maximal 5-second grasp with a DIGIT-grip Model LCD-200 grasp meter<sup>b</sup> with the arm extended. Three grasps with 1-minute rests were made, and the maximal effort was used in the data analysis. Maximal pinches were assessed in a similar manner, with the subjects exerting a 5-second maximal thumb–first finger arm-extended pinch with a B&L Pinch Gauge pinch meter.<sup>c</sup> Three pinches with 1-minute rests were obtained, and the maximal effort was used in the data analysis. Visual analog scales (0mm = no pain; 100mm = incredibly severe pain) of the form that have been validated in the assessment of pain<sup>17-19</sup> were used to quantify subjective assessments, including the main outcome measures of pain experienced in the last 24 hours, tenderness to palpation, and patient's perception of change (benefit).

The laser was calibrated daily with a power meter incorporated in the unit and approximately at monthly intervals with an external (Coherent 210) power meter.<sup>d</sup> Power readings were stable and remained within 5% of the nominal power required for the 204-mW/cm<sup>2</sup> average intensity specified for the study.

Table 5: Signs and Symptoms at 1-Month Follow-Up

	Active Group	Control Group	p*
Main outcome variables			
Pain level in last 24hr <sup>†</sup>	27.2 (17.5)	17.8 (14.0)	.488
Maximal tenderness on palpation <sup>†</sup>	34.9 (30.0)	33.1 (27.0)	.965
Overall change	76.4 (82.0)	82.0 (85.0)	.636
Secondary outcome variables			
Grip strength (kg) <sup>‡</sup>	30.9 ± 30.1	35.4 ± 36.1	.330
Pinch strength (kg) <sup>‡</sup>	5.1 ± 5.0	5.2 ± 5.0	.536
Pain with grasp <sup>†</sup>	33.9 (31.0)	27.6 (18.0)	.808
Pain with pinch <sup>†</sup>	29.3 (24.0)	22.8 (15.0)	.559

\* Wilcoxon's rank sum test (mean given).

<sup>†</sup> Visual analog scale (mm) (mean given). A lower value is equivalent to less pain.

<sup>‡</sup> Values presented as mean ± SD.

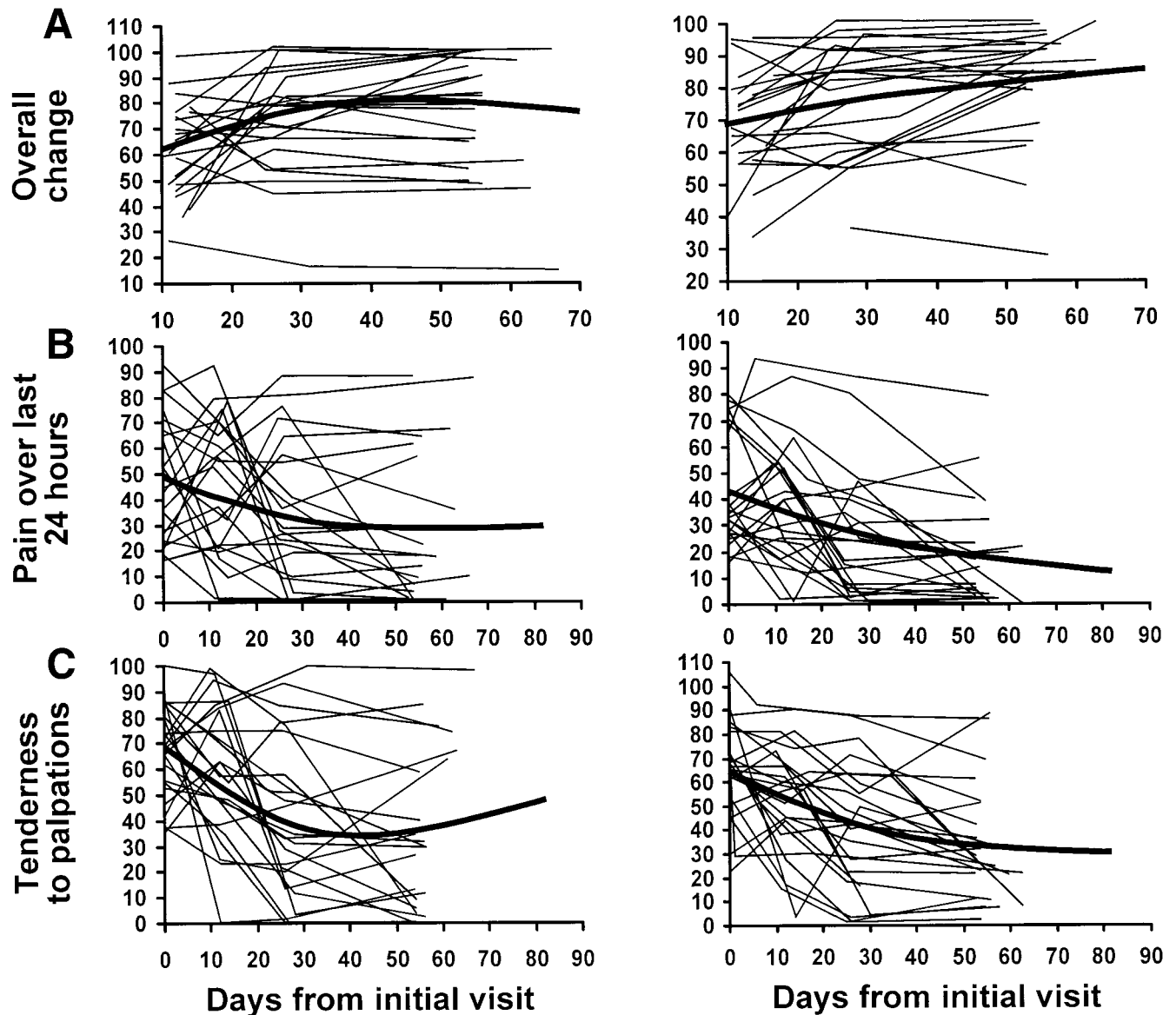


Figure 1. Laser therapy for lateral epicondylitis. Line diagrams comparing (A) the perception of change (treatment benefit) in the members of the (left) laser treated and (right) control groups, (B) the maximal pain reported in the previous 24 hours by the members of the (left) laser treated and (right) control groups, and (C) the maximal tenderness to palpation in the members of the (left) laser treated and (right) control groups. The narrow lines represent the individual subjects; the broader lines are a spline curve indicating the overall trend in each group.<sup>22</sup>

### Statistical Analysis

Statistical analysis was performed by a statistician informed only to distinguish whether there was a difference in response to 2 treatments (ie, treatments A, B). This individual was never at the treatment site or otherwise involved in the study.

Laser therapy efficacy is not established. As a result, expected variances were unknown, and we were unable to perform an *a priori* power analysis to estimate sample size. We therefore adopted an "effect size" approach, postulating that an effect size of .75 or greater (the difference in group means divided by their common standard deviation) was a reasonable goal. On this basis, we determined that sample sizes of 30 patients in each group would provide an 80% power with  $p$  of .05.<sup>20</sup>

The responses of the control and treatment groups were compared between evaluation times by using a nonparametric

Wilcoxon's rank sum test for such continuous variables as visual analog scale measurements. Chi-square tests, or Fisher's exact test when appropriate, were used for nominal data. Comparison of changes from baseline values to subsequent values were assessed using Wilcoxon's signed rank test on differences.<sup>21</sup>

### RESULTS

Sixty-two individuals volunteered for the study and were screened by telephone. Fifty-five of these subjects met the study criteria (eg, duration of symptoms, no treatment within the previous month) and were evaluated; 2 did not meet study criteria (1 was asymptomatic, the other had medial epicondylitis), and 1 chose not to participate. Of the remaining 52 subjects, analysis was restricted to the 47 (23 active, 24 control) who completed at least 11 of the 12 treatments and

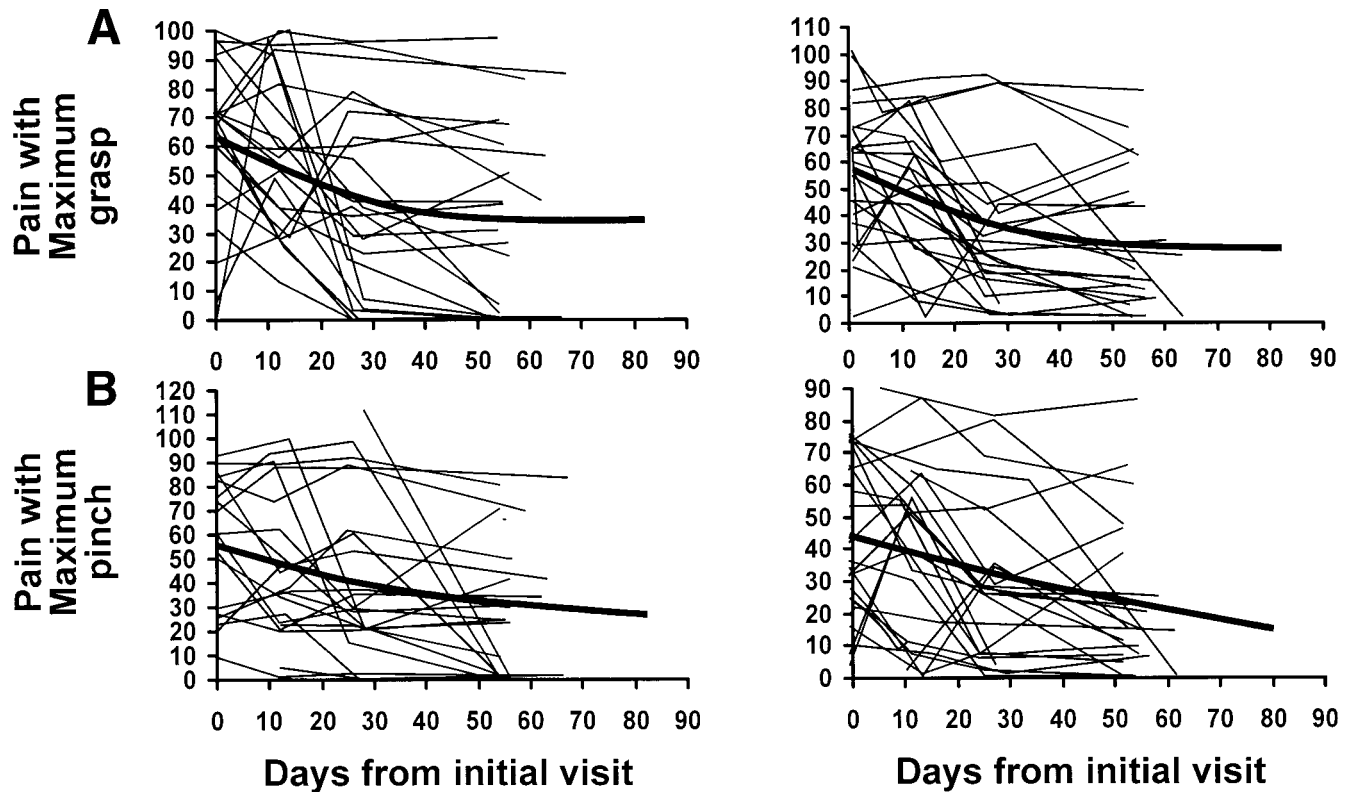


Figure 2. Line diagrams comparing (A) pain with maximal grasp reported by the members of the (left) laser treated and (right) control groups and (B) pain with maximal pinch in the members of the (left) laser treated and (right) control groups. The narrow lines represent the individual subjects, the broader lines are a spline curve indicating the overall trend in each group.<sup>32</sup>

appeared for the evaluation sessions at the beginning, midpoint, and end of treatment. Forty-six subjects (23 active, 23 control) completed at least 11 treatments and returned for their 1-month (28–35d) follow-up evaluation.

Group demographics are listed in table 1. As the table shows, the groups did not differ significantly in terms of activity, duration of symptoms, medication use, gender, age, orthotic use, or previous treatment.

The groups did not differ in terms of outcome. There were no statistically significant differences between them in terms of the primary (pain, tenderness to palpation, level of function assessed with grip strength) or secondary (pain level, pinch strength, pain with grasp and pinch) outcome variables (tables 2-5, figs 1, 2).

Although we did not tabulate the findings, we found that the groups did not differ significantly either during the study or at

the follow-up visit in terms of changes in medication use (all  $p > .374$ ), activity level (all  $p > .593$ ), or orthotic use (all  $p > .547$ ) (chi-square tests). Although measurements of resisted wrist and long finger extensor strength and pain mirrored this lack of benefit, the pattern was more complex for these more subjective manual resistance tests. As table 6 shows, pain with resisted wrist and long finger extension did not show significant changes between the groups at any of the evaluations (all  $p > .084$ , Wilcoxon's rank sum test). However, there was a scattering of findings in the strength associated with these determinations in that strength differences reached statistical significance in 2 isolated instances: at the end of treatment for resisted wrist extension ( $p < .007$ ) and at follow-up for resisted long finger extension ( $p < .022$ ). (It is interesting that the treated subjects were somewhat weaker and more painful than the controls.)

Table 6: Comparison of  $p$  of Resisted Wrist and Long Finger Extension Strength and Pain in the Active and Control Groups

	Baseline	Midpoint of Treatment (Session 6)	End of Treatment (Session 12)	Follow-Up (1mo)
Strength				
Wrist extensor strength	.231	.451	.007*	.096
Long finger extensor strength*	.586	.217	.668	.022*
Pain				
Pain with resisted wrist extension	.084	.205	.084	.455
Pain with resisted long finger extension	.109	.693	.553	.899

All tests are rank sum tests.

\* Treated group minimally stronger than control group in the 3 evaluations in which statistical significance existed.

## DISCUSSION

This study shows that low intensity laser therapy, at least within our parameters, is not effective in treating lateral epicondylitis. In particular, we found that 1.06- $\mu\text{m}$  Nd:YAG radiation did not lessen the pain, tenderness, or limitations of function associated with lateral epicondylitis. An obvious explanation for this lack of effect is that this therapeutic approach is not beneficial for any condition. This view may be true. However, given its wide use and laboratory research finding that laser radiation has measurable effects at the cellular level,<sup>1,10-12,14</sup> it seems too glib to dismiss the approach without further discussion. We discuss a number of issues that may have been pertinent to our study outcome.

First, we studied the effects of a particular laser (ie, a 1.06- $\mu\text{m}$  Nd:YAG CW with an average output power intensity of 204mW/cm<sup>2</sup> with irradiations of 60s/site [12.24J/cm<sup>2</sup>]). Thus, our conclusion is restricted to a specific set of parameters. This distinction is not unimportant because optimal treatment parameters (eg, wavelength, dosage, number of treatment sessions) have not been agreed on.<sup>1</sup> Nevertheless, our approach was appropriate in that we used a laser found successful in the treatment of musculoskeletal pain<sup>16</sup> and a protocol that in many ways (eg, multiple treatment sessions, IR wavelength) mimics clinical practice.<sup>16</sup> Our 5-cm diameter laser aperture was larger than typically used, but because our treatment intensities are similar to those commonly used, a larger aperture merely increases the area of tissue treated and, potentially, our chance of success. One may also question our use of a 1.06- $\mu\text{m}$  wavelength rather than the more typical choices in the .830- to .904- $\mu\text{m}$  region. However, because (1) no wavelength has been shown to be optimally effective, (2) a 1.06- $\mu\text{m}$  wavelength penetrates more deeply into musculoskeletal tissue than shorter wavelengths, and (3) we achieved beneficial results at this wavelength in an earlier study,<sup>16</sup> we believe our choice was appropriate. Finally, the number of treatment sessions could be debated. Using 12 sessions was arbitrary, but represents a clinically reasonable number of treatments and reflects a consensus among laser therapy clinicians and researchers that successful treatment typically requires multiple treatments.<sup>16</sup>

Second, we focused on a specific condition: lateral epicondylitis. We believe this was a reasonable model against which to test laser therapy because it is superficial enough to allow laser beam penetration to depths compatible with the dysfunction commonly and frequently treated with laser therapy. Our lack of success persuaded us to reexamine our hypotheses. It turns out that lateral epicondylitis may be a particularly difficult hurdle. To begin with, lateral epicondylitis has remained refractory to conservative and surgical care despite its description more than 100 years ago. In addition, research currently emphasizes the chronic, smoldering, subacute nature of this condition.<sup>23-26</sup> As a result, the inflammatory aspects of musculoskeletal injury, for which laser therapy is often promoted as being particularly effective,<sup>1</sup> may not be as prominent as might be expected. Finally, a review of laser therapy research (albeit in studies that used lasers with much smaller apertures than ours) reveals mixed findings: some reports find that lateral epicondylitis is minimally or unresponsive to irradiation,<sup>27,28</sup> whereas others find treatment helpful.<sup>29</sup>

Third, it might be argued that poor diagnosis, evaluation techniques, or inappropriate sites of laser treatment prevented the detection of treatment benefits. We do not believe this is the case. Lateral epicondylitis is typically a clinical diagnosis, and our approach mirrored the diagnostic techniques of clinical practice.<sup>30,31</sup> We did not obtain forearm x-rays, but because x-rays will show calcific changes in lateral epicondylitis in only

25% to 50% of cases,<sup>32</sup> we do not believe they would have improved subject selection. Our evaluation criteria, although mostly semiquantitative (eg, pain, tenderness, perception of benefit), also included some quantitative strength data. Our choice of treatment sites was appropriate and, if anything, erred on being conservative. We had initially planned to irradiate at only 4 points: 3 contiguous locations over the proximal extensor apparatus and a fourth on the distal tendon. However, the manufacturer<sup>a</sup> reported success in a pilot protocol that included these points as well as 2 over the median epicondyle and 1 at the volar wrist crease. Because there is no evidence that additional locations of irradiation would interfere with therapy effectiveness, it seemed prudent to include these additional points.

Fourth, subject selection might have affected our results. Again, we do not believe this is the case. Group demographics (table 1) did not differ in either a statistically significant or systematic manner. In addition, the groups remained balanced throughout the study (23 in the treated group, 23-24 in the control group). Our approximately 10% dropout rate should not have affected our conclusions because a formal intention-to-treat analysis would merely reinforce our findings of a lack of treatment benefit.

Last, masking is often difficult in therapeutic trials. Fortunately, our laser therapy device and protocol were almost ideal in their ability to ensure adequate masking. The 1.06- $\mu\text{m}$  laser wavelength used lies in the IR portion of the spectrum and would not have been visible even if therapists and subjects were not wearing goggles opaque to this wavelength. In addition, treatments were imperceptible, and neither therapists nor subjects could assess group assignment on this basis.

## CONCLUSION

This study does not support the use of laser therapy in the treatment of lateral epicondylitis. However, it is important to note that this therapeutic approach may be effective in other conditions or with other parameters. Further studies on both the basic and clinical levels are warranted.

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#### Suppliers

- a. LaserBiotherapy, Inc, 5430 Glen Lakes Dr, Ste 150, Dallas, TX 75234.
- b. NK Biotechnical Corp, 10850 Old County Rd, Ste 15, Minneapolis, MN 55441.
- c. B&L Engineering, 3002 Dow Ave, Ste 416, Tustin, CA 92780.
- d. Coherent 210 power meter; 5100 Patrick Henry Dr, Santa Clara, CA 95054.