Low-Energy Laser Treatment and Exercise for Chronic Low Back Pain: Double-Blind Controlled Trial

Robert G. Klein, MD, Bjorn C. Eek, MD

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• Twenty patients with chronic low back pain were enrolled in a randomized double-blind trial to test the efficacy of low-energy laser biostimulation combined with exercise. Ten patients received low-energy gallium-arsenide laser treatment, and ten received placebo laser treatment. Both groups were also placed on an active exercise program. Visual analogue and disability pain scores were assessed pretreatment and one month posttreatment and showed significant ($p < .02$) improvements in both groups, but no relative advantage was found for either group. Objective parameters using computerized triaxial measurements of range of motion, isometric torque, and isodynamic velocity were also performed before and after treatment. There were significant improvements in objective parameters in both the laser and placebo groups, but no relative advantage accrued to either group. Under the conditions of this study, low-energy laser stimulation plus exercise did not provide a significant advantage over exercise alone.

KEY WORDS: Backache; Laser; Ligament

Uncontrolled studies have suggested that low-energy laser biostimulation can be used to treat neck and back pain with 70% to 80% of patients reporting significant symptomatic relief.[1] Our study was initiated to determine whether low-energy laser stimulation, when combined with a program of exercises, could produce an improvement in subjective and objective indices of back pain when compared with exercise alone. The advent of a computerized triaxial system allowing measurement of lumbar function provided the opportunity to study objective parameters in addition to the usual subjective indices to document pretreatment vs posttreatment changes.

High-power laser applications (10 to 100W) for selected surgical procedures and hemostasis are well accepted in the US, but the FDA has mandated further testing of low-power lasers to prove their efficacy. The low-energy gallium-arsenide infrared laser is ideally suited for a double-blind study since the laser light is invisible and emits no heat or other physically detectable indication when it is activated.

METHODS

Patient Selection

Twenty-four patients with chronic low back pain were interviewed and examined after recruitment by advertisement, and 20 were accepted for entry into the study. Criteria for entry were chronic low back pain of at least one year, age 21 to 55 years, not pregnant, no prior back surgery, not more than ten pounds overweight, and not involved in litigation or disability claims. Patients with acute exacerbations of chronic pain were excluded. All 20 patients shared clinical features of back pain with prolonged maintenance of one posture, such as prolonged sitting, standing, or bending, and temporary relief of symptoms with changing positions or walking. Each patient was examined clinically for any signs of radiculopathy. Straight-leg raise tests and sciatic tension signs were normal or negative, and no reflex asymmetry, loss of sensation, or focal weakness was noted in the 20 patients included in the trial.

The study was approved and monitored by the Sansum Medical Research Foundation Institutional Review Board. All patients gave signed informed consent.

Randomization and Blinding

The manufacturer of the laser device used in these studies (Omniprobe™ laser biostimulation unit[a]) modified the unit by installing a toggle switch with two positions, only one of which activated the laser. Patients were assigned to either group A or group B via a computer-generated random numbers table, and the toggle switch was set to the appropriate position for each treatment. Neither the physicians examining the patients nor the therapists treating and testing the patients were aware of whether the patient was receiving the laser treatment or the placebo laser treatment. The code was not broken until after the data analysis was completed. The decision was made before initiating the study to treat an initial group of 20 patients. Additional patients were to be recruited if any trend toward significant differences between groups could be discerned.

Statistical Analysis

Time (before vs after) and treatment (laser vs placebo) effects for continuous variables were assessed by a repeated

From the Department of Medical Orthopedics, Sansum Medical Clinic, Santa Barbara, CA.

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Reprint requests to Dr. Klein, Department of Medical Orthopedics, Sansum Medical Clinic, PO Drawer LL, Santa Barbara, CA 93102.

measures analysis of variance using the Systat program; F values were calculated and p values were derived from them. The Student t-test was used to analyze subjective and demographic data. All data are presented as mean ± standard deviation. A one-sided p value less than .05 was considered significant.

Subjective Data

Visual analogue pain scores were used with 0cm representing absence of pain and 7.5cm representing maximal pain. Disability scores were derived from a previously validated questionnaire consisting of 24 items.[9] Subjective data were collected one week before initiation of treatment and repeated one month after completion of treatment.

Objective Data

Objective measurements of lumbar function were performed with a commercially available computerized isodynamic system, the Isotechnologies B-200.[b] This device provides valid and reliable information about the functional characteristics of the low back.[8] The B-200 uses a restraint system to effectively restrict the motion of the trunk to the lower back. A slide mechanism on the thoracic restraint permits obligatory spinal elongation and thus minimizes any restraint-imposed compressive forces.

Measurements from the B-200 were performed by a physical therapist according to a standardized protocol. Parameters measured included range of motion, isometric torque, and isodynamic velocities in all three major axes. The record of each patient was scrutinized to be certain that a reproducible effort was attained, indicating full cooperation. Recordings were made one week before initiation of treatment and were repeated one month after completion of treatment.

Twelve additional chronic low back patients with the same clinical features as the experimental group volunteered to have B-200 reproducibility testing performed on two occasions with an average of 14 days between tests. None of these patients were treated with exercise, medication, or other modalities in the interval between the two tests.

Laser Stimulation

A gallium-arsenide class I multihead pulsed-output infrared laser was used with a frequency of 1000Hz, a pulse width of 200 nanoseconds, and a wavelength of 904 nanometers. Application of the laser was external over a series of standardized fields designed to include the L4 to L5 and L5 to S1 apophyseal capsules, dorsolumbar fascia, and interspinous ligaments, as well as the gluteal fascia and posterior sacroiliac ligaments. The multihead laser consists of ten 2-W laser heads in a 12-cm linear array which permits simultaneous point stimulation of 1cm^2 of tissue at each of the ten sites. This reduces tissue treatment time tenfold and allows rapid treatment of large tissue areas. A stimulation time of four minutes was used at each point, producing an energy at each point of approximately 1.3J/cm^2. Approximately 20 minutes of total stimulation time was needed to cover the entire area of treatment for each patient. Each patient was treated three times per week for four weeks.

Table 1: Subjective Scores*

Variable	Pretreatment	Posttreatment	p value
Laser visual analogue	3.0±1.2	1.7±1.4	.003
Placebo visual analogue	3.3±1.1	2.1±1.2	.011
Laser disability	5.4±3.4	3.6±2.1	.019
Placebo disability	5.9±2.6	2.9±1.3	.005

*Significant improvement in both scores in both groups.

Exercise Program

All patients were placed on a standardized home exercise program consisting of 50 full-forward flexion exercises performed in the standing position followed by 25 extension exercises twice daily. All patients were instructed to walk briskly for 20 minutes each day and to perform two sets of knee flexion coupled with hip abduction exercises each day. These exercises were to be started on the first day of the study and continued at least until completion of all objective and subjective measurements. Each patient was questioned and repeatedly encouraged regarding compliance with the exercise program.

RESULTS

The laser and placebo groups were comparable at entry, respectively in terms of age (44.1±7.9 years vs 41.3±10.7 years), years of pain (8.3±6.8 vs 9.2±8.6), disability scores (5.4±3.3 vs 5.9±2.6), visual analogue scores (3.0±1.2 vs 3.3±1.1), and gender (two men in the laser group and three in the placebo). No patient in either group reported discomfort related to the laser or exercise treatment, and no patient complained of an increase in pain at the conclusion of the study.

Subjective Data

There were significant improvements in visual analogue pain and disability ratings posttreatment within each group (table 1), but no difference was noted between laser and placebo laser groups in posttreatment visual analogue ($p = .493$) or disability scores ($p = .919$).

Objective data

Computerized data from the B-200 demonstrated no significant difference in pretreatment or posttreatment objective pa-

Table 2: Range of Motion (Degrees ± SD)

Variable	Pretreatment	Posttreatment
Laser rotation	33.3±8.1	37.8± 7.6*
Placebo rotation	35.5±5.9	37.9± 8.4*
Laser flexion	52.5±8.3	56.7± 4.8*
Placebo flexion	49.8±8.9	53.4±10.4*
Laser extension	32.6±5.6	33.2± 2.7
Placebo extension	33.2±5.1	33.1± 3.7
Laser side flexion	31.7±4.6	36.5± 6.6†
Placebo side flexion	34.8±6.1	36.7± 5.6†

Rotation and side flexion torques are the average of left-sided and right-sided values. * $p < .05$; † $p < .02$

Table 3: Isometric Torque (Foot=pounds)

Variable	Pretreatment	Posttreatment
Laser isometric rotation	35.4±12.4	44.5±18.2*
Placebo isometric rotation	37.9±19.5	44.6±20.3*
Laser isometric flexion	54.5±23.4	61.9±28.2
Placebo isometric flexion	60.7±40.7	54.4±29.6
Laser isometric extension	83.5±33.9	86.2±33.5
Placebo isometric extension	80.9±28.0	82.9±30.7
Laser isometric side flexion	63.1±26.3	66.1±24.1
Placebo isometric side flexion	65.3±28.9	69.3±27.3

Rotation and side flexion torques are the average of left-sided and right-sided values. * $p<.01$

rameters between the laser and placebo groups. Multiple variables were assessed, and results are shown in tables 2 to 4. The laser and placebo groups showed overall improvements in range of motion posttreatment with increases in rotation ($p<.05$), flexion ($p<.05$), and side flexion ($p<.02$). Isometric rotation ($p<.01$) was the only isometric parameter to improve significantly posttreatment in the two groups. Velocity testing showed the most marked and consistent changes in comparing laser and placebo pretreatment to posttreatment values. Velocity of rotation ($p<.01$), flexion ($p<.001$), extension ($p<.001$), and side flexion ($p<.001$) all showed significant before and after test improvements in the laser and placebo groups. Interactional analyses did not demonstrate any significant differences between laser and placebo groups for any of the objective parameters.

Reproducibility Study

Only one variable (side flexion range of motion) showed a difference ($p<.05$) between the initial evaluation (36.0±5.9) and the repeat testing (37.6±5.4). This could be attributed to the minimal variance across subjects so that any difference between pretest and posttest results can be attributed to the precision of the test. There was no suggestion of a significant learning effect based on the data.

DISCUSSION

In vitro studies of human skin fibroblasts have demonstrated accelerated collagen synthesis and increased wound healing using low-power gallium-arsenide infrared and helium-neon lasers.[2,3] The postulated mechanism of action is an acceleration of procollagen gene expression leading to an increase in type I and type III mRNA levels.[10] The gallium-arsenide laser is known to penetrate to depths of 1cm to 5cm in soft tissue. This depth of penetration should be adequate to treat the major posterior ligaments, fascia, and apophyseal capsules of the lower back in the patients of normal body weight recruited for our study.

Table 4: Maximal Velocity (Degrees/sec)

Variable	Pretreatment	Posttreatment
Laser velocity rotation	69.1±21.4	84.9±29.9*
Placebo velocity rotation	73.1±25.7	96.2±48.6*
Laser velocity flexion	76.1±22.1	88.6±28.5†
Placebo velocity flexion	77.4±34.2	93.5±41.8†
Laser extension velocity	75.9±23.4	93.0±33.6†
Placebo extension velocity	79.1±32.6	94.2±36.9†
Laser side flexion velocity	86.4±20.4	112.3±33.0†
Placebo side flexion velocity	88.6±30.4	102.8±41.2†

Rotation and side flexion velocities are the average of left-sided and right-sided values. Velocity is measured against a fixed resistance of 15 foot-pounds in rotation, 25 foot-pounds in flexion/extension, and 20 foot-pounds in side flexion. * $p<.01$; † $p<.001$

No prior double-blind study of low-energy laser biostimulation for low back pain was available in the literature for comparison, and, therefore, multiple assumptions were necessary in the design of this study. The failure to demonstrate a relative advantage to the laser group over the placebo laser group may relate to the uncertainty inherent in these assumptions. There is no certainty that sufficient laser energy was delivered to the appropriate tissues in the low back. This may have been due to inadequate depth of penetration, inadequate exposure times, or frequency of laser treatment, or misconceptions regarding the tissues or mechanisms responsible for the genesis of low back pain in this group of patients. Alternatively, the relative effectiveness of the simple exercise program may have concealed any mild laser-induced effect.

A basic assumption in using the laser for presumed acceleration of collagen synthesis is that inadequate connective tissue support (dorsolumbar fascia, posterior ligaments, apophyseal capsules) plays an important role in the genesis of back pain in the type of patient described in this study. A previous double-blind study in a similar group of patients using a connective tissue proliferant (sclerosant) indicated an advantage to the proliferant injection/exercise group over the saline injection/exercise group. These injections were placed into approximately the same sites as the laser, and the exercise program in the present study was similiar to that used in the injection study.[7]

The simple repetitive-movement exercises used in our study were chosen to encourage the connective tissue proliferation that is postulated to occur with laser therapy. Tissue tension is now recognized as an effective stimulus for connective tissue proliferation, and a variety of studies have clearly demonstrated the responsiveness of connective tissues to movement and mechanical stimuli.[11]

Mayer and coworkers[5] have suggested that the lack of objective functional capacity measurements is a likely cause for much of the confusion in spine care. We used a powerful, new, objective tool to help determine efficacy of treatment. Isodynamic (isoinertial) measurements assess the contraction of muscles against a constant preset load. The velocity of this movement can accelerate or decelerate if the generated torque is greater or smaller than the load. This differs from isokinetic contraction in which the rate of shortening and lengthening of the muscle is constant.

Our study showed significant pretreatment vs posttreatment improvements in velocity of movement in all three major axes in the laser and placebo group of patients. Velocity of movement has previously been shown to be an excellent quantitative indicator of low back function and a means of monitoring the rehabilitative progress of patients with low back pain.[4] Range of motion testing demonstrated significant improvements in rotation, flexion, and side flexion, whereas isometric torque improved significantly only in rotation.

Reproducibility testing was done to be certain there was no significant "training effect" by repeating the B-200 computerized testing in patients with chronic pain. Patients with back

pain might be apprehensive at the time of initial testing and less so on repeat testing, or there might be a "learning effect" from using the computerized equipment that would artifactually improve the results of retesting. The data do not suggest a significant learning or training effect and make it likely that the improvements in range of motion, velocity, and isometric torque are valid.

The objective and subjective data generated in this study give strong support to the importance of an active and repetitive exercise program in the treatment of chronic low back pain. Recent studies on functional restoration of patients with chronic low back pain have emphasized the importance of an active exercise program in the rehabilitation process.[6]

We conclude that low-energy laser stimulation under the short-term conditions of this study does not appear to provide any advantage over exercise alone.

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Suppliers

a. Physio Technology, Inc., 1925 W 6th Street, Topeka, KS 66606
b. Isotechnologies, Elizabeth Brady Road, P.O. Box 1239, Hillsborough, NC 27278.