Laser Therapy: A Randomized, Controlled Trial of the Effects of Low-Intensity Nd:YAG Laser Irradiation on Musculoskeletal Back Pain

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ABSTRACT. Basford JR, Sheffield CG, Harmsen WS. Laser therapy: a randomized, controlled trial of the effects of low-intensity Nd:YAG laser irradiation on musculoskeletal back pain. Arch Phys Med Rehabil 1999;80:647-652.

Objective: To assess the effectiveness of low-intensity laser therapy in the treatment of musculoskeletal low back pain.

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

Setting: A physical medicine and rehabilitation clinic.

Participants: Sixty-three ambulatory men and women between the ages of 18 and 70yrs with symptomatic nonradiating low back pain of more than 30 days' duration and normal neurologic examination results.

Intervention: Subjects were bloc randomized into two groups with a computer-generated schedule. All underwent irradiation for 90 seconds at eight symmetric points along the lumbosacral spine three times a week for 4 weeks by a masked therapist. The sole difference between the groups was that the probes of a 1.06μm neodymium:yttrium-aluminum-garnet laser emitted 542mW/cm^2 for the treated subjects and were inactive for the control subjects.

Main Outcome Measures: Subject's perception of benefit, level of function as assessed by the Oswestry Disability Questionnaire, and lumbar mobility.

Results: The treated group had a time-dependent improvement in two of the three outcome measures: perception of benefit and level of function. These results were most marked at the midpoint evaluation ($p < .005$, $p < .01$) and end of treatment ($p < .017$, $p < .001$) but tended to lessen at the 1-month follow-up ($p < .10$, $p < .004$). Lumbar mobility did not differ between the groups at any time. All tests were two-sample t tests with unequal variances.

Conclusions: Treatment with low-intensity 1.06μm laser irradiation produced a moderate reduction in pain and improvement in function in patients with musculoskeletal low back pain. Benefits, however, were limited and decreased with time. Further research is warranted.

THE IDEA THAT LASER radiation at intensities too low to produce significant heating has beneficial therapeutic effects may seem absurd. Nevertheless, this treatment is in wide use, and the concept is neither new nor completely bizarre because the electromagnetic spectrum has a well established role in medicine. For example, sunlight was used by the ancient Greeks to heal and strengthen. Today, ultraviolet and visible light are used as bactericidal agents as well as in the treatment of psoriasis and mood disorders. In addition, short-wave diathermy, which merely uses a longer-wavelength portion of the spectrum, is a common physical therapy treatment.[1,2]

Laser therapy is based on the belief that laser radiation, and possibly monochromatic light in general, is able to alter cellular and tissue function in a manner dependent on the characteristics of light itself (eg, wavelength, coherence).[3] Initial work with this therapy began in eastern Europe more than 30 years ago[4-7] with anecdotal and poorly controlled reports that extremely low-power (≤1mW) laser irradiation altered hair growth and bacterial processes and accelerated wound healing[3-7] independently of heating.[3,8-10] These first communications were often incomplete and difficult to access. Nevertheless, they caught the attention of investigators in Europe and the Soviet Union. With time, interest has spread, research has continued, rigor and masking have improved, and clinical use has grown. Low-intensity lasers (often also known as "low-energy" or "low-power" lasers) are now used in as many as 30% to 40% of physical therapy, dental, and sports clinics in many parts of the world to treat soft tissue injuries, poorly healing wounds, pain, and inflammation.[3,11-13] Although "laser therapy" remains controversial[3,14-16] and has not received US Food and Drug Administration (FDA) approval for clinical use, it appears safe,[3,17,18] and interest is growing in the United States also.[3]

Early work involved a wide variety of visible and infrared (IR) devices. However, over the years approaches have converged, and today clinical treatment and research emphasize infrared lasers and diodes with wavelengths between .78 and 1.06μm. Initially, lasers were very low in power, apertures were small, and dosages were often restricted to 1 to 4J/cm^2 at a treatment site.[3-6] However, the lasers in common use have increased in power (now often 30 to 100+mW). Aperture size has also tended to grow, and dosages (in J/cm^2) have either remained the same or grown modestly. In any event, the energies and powers used in laser therapy typically are 30 to more than 100 times less than those involved in ultrasound and short-wave diathermy treatments of comparable disorders.

We chose to systematically study the potential benefits of this controversial therapy. Because laser therapy is often used to treat musculoskeletal conditions, we decided to investigate the effectiveness of low-intensity laser irradiation on a common musculoskeletal complaint. In particular, we performed a double-masked, randomized, placebo-controlled clinical evaluation of the efficacy of a 1.06mm (IR) neodymium:yttrium-aluminum-garnet (Nd:YAG) laser in the treatment of musculoskeletal low back pain. Our hypothesis was that treatment

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would result in lessened pain, an enhanced level of function and improved lumbar mobility.

SUBJECTS AND METHODS

The protocol was reviewed and approved by the institutional review board of our institution. After approval, 63 otherwise healthy individuals between the ages of 18 and 70 years with nonradiating low back pain of more than 30 days' duration were recruited with announcements in our institutional newsletter and the local newspaper and by referral from local physicians and chiropractors. Both men and women were accepted for entry, but, although no established risk in pregnancy is known, women were required to be postmenopausal or practicing an effective means of birth control (pregnancy tests were obtained in women of 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 (eg, fusion), did not preclude participation in the study as long as there had been no treatment of this problem by a physician, physical therapist, chiropractor, or other health care provider in the previous 30 days. Individuals who had received corticosteroids for any reason in the last 30 days were also excluded. Analgesic and nonsteroidal antiinflammatory medication use was not encouraged but was monitored as an experimental variable.

Diagnosis of musculoskeletal back pain was made by a physician experienced in musculoskeletal diseases and depended on normal neurologic examination results (ie, normal appreciation of light touch and sharpness, symmetric deep tendon reflexes [quadriceps, internal hamstrings, gastrocsoleus], normal lower extremity muscle strength and straight leg raising) as well as complaints of localized pain and tenderness in the vicinity of the lumbosacral spine. Physical examination also assessed lumbosacral mobility and tenderness to palpation. Subjects were excluded if they complained of radicular pain, described pain extending below their buttocks, or noted changes in either bowel or bladder function or lower extremity strength or sensation. Lumbar spine x-rays were required to have been taken within the last year and, if not taken, were obtained before entrance into the study. Subjects were also asked to complete a pain diagram.

After a successful examination and history, the study participants were bloc randomized with a computer-generated schedule into two groups. Each group was familiarized with the study design and received an identical introduction to musculoskeletal back pain and treatment options by a masked therapist. Treatment was performed in a standard manner by a masked therapist with the subjects removing their shirts (women were permitted to keep their brassieres on) and lying prone on a plinth. Both the therapist and the subject wore protective goggles during treatment. The therapist scrubbed the lumbar paraspinal muscles with an alcohol-soaked gauze pad. Both groups were then irradiated for 90 seconds at two sites simultaneously at each of four equally spaced levels (a total of 8 points) along the L2 to S3 paraspinal tissues on a three times a week, 4-week schedule. Irradiation was performed with a 1.06μm Nd:YAG continuous-wave laser[a] having a 2.5-cm diameter applicator. The only difference in treatment between the groups was that the active group was irradiated with the probes emitting an average intensity of 542mW/cm^2 while the control group was "irradiated" with the same, but inactive, probes. Subjects were allowed to make up a maximum of two 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 10 or more sessions and returned for a follow-up visit. Subjects were evaluated before the first treatment, at the midpoint (sixth session) and at the end (twelfth session) of treatment as well as at a "1-month" follow-up 28 to 35 days after the last treatment. Each evaluation was performed by an experienced and masked physician and therapist not involved in the treatment and consisted of administration of a validated back pain questionnaire (The Oswestry Disability Questionnaire)[19,20] and repetition of the questions and examination given at the time of entrance into the study. Lumbar mobility was assessed with a modification of the Schober test[21] by marking points on the skin 5cm above and 5cm below the L5-S1 junction as the subjects stood in a neutral position and measuring the excursion of these points when they bent forward to their maximal extent. Subjects were also asked about changes in medication use, activity level, perception of benefit, pain nature, and whether they had suffered any adverse effects from treatment. Visual analog scales (0 mm, no pain; 100 mm, incredibly severe pain) have been validated in the assessment of pain[22-24] and were used to quantify subjective assessments.

The laser was calibrated daily with a power meter incorporated into the unit and at approximately weekly intervals with an external (Coherent 210) power meter. Power readings were stable and remained within 6% of the nominal power required for the 542mW/cm^2 average intensity specified for the study except for the last four subjects (two in each group), in whom the output of one probe decreased 40% from the nominal level.

Statistical Analysis

The responses of the control and treatment groups were compared at individual points using a two-sample t test with unequal variances for continuous variables such a visual analog scale variables. The Fisher Exact Test for an ordered outcome was used for nominal data unless criteria for the χ^2 test were met. Comparison of baseline with final states was done using a matched analysis (two-sample t test with unequal variances test on the change scores).[25] We believed a reduction in symptoms of 35% to 40% would represent a clinically significant benefit of treatment. On this basis, our study design with 30 subjects in each group would have 80% power ($\alpha = .05$) to detect a treatment effect.

RESULTS

Sixty-three subjects were evaluated; two chose not to participate. Of the remaining 61 subjects, analysis was restricted to the

Table 1: Demographics

Subject Characteristics	Active Group	Control Group	p
On feet most of day (%)	7/30 (23)	7/29 (24)	.882*
Female (%)	12/30 (40)	16/29)	.243*
Age (yrs)	47.8 (48.0)	48.2 (49)	.904†
Nature of pain (% described as "burning/aching")	26/30 (87)	21/29 (72)	.174*
Symptom duration (mo)	6.9 (4.5)	12.8 (6.5)	.301†
"Flat back" on initial examination	20/29 (69)	18/28 (64)	.708*
Previous treatment with physical therapy, injection or chiropractic	17/30 (57)	20/29 (69)	.329*
Analgesic use (no./day)	4.6 (4.0)	4.4 (4.0)	.605†
Lumbar spine X-rays showing changes compatible with mild to moderate degenerate spine disease (%)	21/30 (70)	24/28 (86)	.152*

Data represent means (medians).
* χ^2 test.
† Two-sample t test with unequal variances.

Table 2: Signs and Symptoms at Initial Evaluation

	Active Group	Control Group	p	Difference in Means (Active − Control)	95% CI
Main outcome variables					
Oswestry score	21 (22)	25 (22)	.107	−3.5	−7.8, 0.8
Lumbar mobility (cm)	13.9 (14.0)	14.2 (14.2)	.278	−0.3	−0.8, 0.2
Secondary outcome variables					
Maximal tenderness on palpation*	24.7 (20.8)	27.1 (23.0)	.694	−2.5	−14.9, 10.0
Maximal pain in the last 24 hours*	35.2 (29.0)	37.4 (36.0)	.672	−2.2	−12.6, 8.2
Pain with bending	2.6 (2.5)	2.9 (2.0)	.671	−0.3	−1.6, 1.0
Pain with extension	2.3 (2.0)	2.4 (2.0)	.851	−0.1	−1.4, 1.2

Data represent means (medians).
* Visual analog scale (mm). Lower values indicate less pain.
† Two-sample test with unequal variances.

59 who completed at least 11 of the 12 treatments and appeared for the evaluation sessions at the beginning, midpoint, and end of treatment. Fifty-six patients (27 active, 29 control) completed at least 11 treatments and returned for the 1-month (28- to 35-day) follow-up evaluation (one follow-up visit was delayed by 20 days because of subject unavailability).

The demographics of the groups are outlined in tables 1 and 2. As shown, the groups did not differ significantly is terms of activity, gender, age, previous treatment, or initial examination.

The groups did differ in outcome. The group that received irradiation reported a consistent, time-dependent, statistically significant improvement compared with controls in two of the three main outcome variables, ie, in their perception of treatment benefit and their level of activity (as measured by the Oswestry questionnaire; tables 3, 4, and 5; figs 1 and 2). Secondary variables such as the severity of their pain tended to show similar trends (tables 3 through 5). These results were consistent and followed a general pattern: improvement as treatment continued from baseline to the sixth and twelfth sessions. At the 1-month follow-up, benefits lessened but tended to still persist.

We found no consistent differences between the groups in terms of lumbar mobility or secondary variables such as tenderness to palpation or pain with bending or straightening (tables 3 through 5; fig 1). Although the information is not tabulated, we did not find that the nature of pain, lumbar flattening, orthotic use, or analgesic consumption varied significantly between the groups (χ^2 and Fisher's Exact Test). Side effects from treatment were negligible. There was a tendency for the active group to report a mild "warmth" more often during treatment, but this tendency did not reach statistical significance (Fisher's Exact Test).

DISCUSSION

This study shows that low-energy laser therapy, at least within the parameters of this study, is capable of improving the function and lessening the discomfort of individuals with musculoskeletal low back pain. However, there are a number of caveats.

First, the benefits in terms of lessened pain and improved function, although statistically significant, were rather modest and tended to lessen with time (tables 3 through 5; figs 1 and 2). Second, our study focused on a specific group: ambulatory people with subacute and chronic mild to moderate pain. Extension of benefits to other groups may be reasonable but cannot be done from our data. Third, although the intensity of our field, 542mW/cm^2, is similar with that delivered at the apertures of many other low-intensity lasers, our large 2.5-cm diameter applicator allowed us to treat areas far larger than are typical in laser therapy studies. Fourth, pain decreased and function improved in the treated group, but more objective (and less meaningful clinically) measures such as lumbar mobility and tenderness to palpation did not change. We believe the reasons for this apparent dichotomy are twofold. First, lumbar mobility is a relatively insensitive measure, and our subjects tended to have chronic pain (table 1). Thus, even with a

Table 3: Signs and Symptoms at Midpoint Evaluation

	Active Group	Control Group	p*	Difference in Means (Active − Control)	95% CI
Main outcome variables					
Patient perception of benefit*†	29.1 (29.0)	41.6 (44.0)	.005	−12.5	−21.0, −3.9
Oswestry score	17.2 (16.0)	22.9 (24.0)	.010	−5.8	−10.1, −1.4
Lumbar mobility (cm)	14.0 (14.1)	14.4 (14.5)	.092	−0.4	−0.9-0.1
Secondary outcome variables					
Maximal pain in the last 24 hours†	25.1 (20.5)	38.6 (34.5)	.017	−13.5	−24.4, −2.5
Pain severity relative to initial evaluation†	31.3 (30.0)	42.8 (44)	.010	−11.5	−20.1, −2.8
Pain with bending	1.3 (0)	2.2 (0)	.185	−0.9	−2.2, 0.4
Pain with extension	1.2 (0)	2.2 (1.0)	.126	−1.0	−2.2, 0.3
Maximal tenderness on palpation†	18.3 (6.0)	34.1 (28.0)	.033	−15.8	−30.3, −1.4
Tenderness on palpation relative to initial evaluation†	29.8 (31.5)	37.8 (42.0)	.124	−8.0	−18.3, 2.3

Data represent means (medians).
* Two-sample *t* test with unequal variances.
† Visual analog scale (mm). Lower values indicate less pain.

Table 4: Signs and Symptoms at Last Treatment

	Active Group	Control Group	p*	Difference in Means (Active − Control)	95% CI
Main outcome variables					
Patient perception of benefit†	21.5 (16.8)	35.0 (39.0)	.017	−13.4	−24.3, −2.6
Oswestry score	13.3 (14.0)	22.6 (22.0)	.001	−9.3	−14.7, −4.0
Lumbar mobility (cm)	14.0 (14.2)	14.0 (14.0)	.949	0	−0.4, 0.4
Secondary outcome variables					
Maximal pain in the last 24 hours†	17.1 (15.8)	32.8 (28.5)	.007	−15.7	−26.8, −4.5
Pain severity relative to initial evaluation†	22.2 (18.3)	36.1 (42.0)	.015	−13.9	−25.1, −2.8
Pain with bending	1.1 (0)	2.3 (1.0)	.036	−1.3	−2.4, −0.1
Pain with extension	1.3 (0)	2.4 (1.0)	.098	−1.1	−2.4, 0.2
Maximal tenderness on palpation†	19.1 (9.8)	25.7 (15.0)	.310	−6.6	−19.4, 6.3
Tenderness on palpation relative to initial evaluation†	27.0 (23.8)	33.3 (42.0)	.227	−6.3	−16.7, 4.0

Data represent means (medians).
* Two-sample *t* test with unequal variances.
† Visual analog scale (mm). Lower values indicate less pain.

lessening of pain, it is not clear that mobility would improve enough for us to detect a change. Second, although all of our subjects had low back pain, tenderness to palpation was an insensitive measure because many subjects described their pain as "deep" and had a limited tenderness to palpation.

Another point that should be made is that our conclusions are restricted to the parameters of our study. This is not a trivial point because optimal treatment parameters (eg, wavelength, dosage, number of treatment sessions) have not been established.[3] Nevertheless, we believe our approach, which used an IR laser to treat a common musculoskeletal problem, mimics laser therapy in clinical practice.[3] It might be argued that our laser aperture was larger than typical. This argument is correct, but our treatment intensities are in line with those in common use; therefore, we believe the larger aperture merely increased our chances of detecting benefits from treatment. The choice of 12 treatment sessions might also be questioned. This choice was arbitrary but seemed to represent a clinically reasonable number and to reflect the consensus in the laser therapy community that multiple sessions are necessary to obtain optimal results.[3]

A related issue is whether the characteristics of our subjects affected our results. Again, with the qualification noted in the next paragraph, we do not think so. In particular, as table 1 shows, the demographics of the treated and control groups did not differ to a statistically significant extent. Although there was a tendency for the treated group to have had their symptoms a shorter time than the control group (a median of 4.5 vs 6.5 months), the variances in both groups were large, and this difference did not reach statistical significance ($p = .301$).

We were fortunate to have an exceptionally reliable group of subjects, a tendency that was probably influenced by the fact that treatment was prompt, quick (<10min), and not painful. Even so, as is shown in the first paragraph of Results, only 2 of the 61 subjects (3.3%) who entered the study did not complete treatment, and 56 of these 59 (ie, 95%) returned for reevaluation at the follow-up visit. This behavior gave our study an ability to detect changes that would have been obscured by a group in which there were more dropouts and missed sessions.

In conclusion, laser therapy has shown a tenacious ability to weather disbelief and lack of knowledge. Our study tends to show that there is some credibility for this approach, at least in the area of musculoskeletal medicine. Further studies with larger subject numbers and parameter refinements are warranted.

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

	Active Group	Control Group	p	Difference in Means (Active − Control)	95% CI
Main outcome variables					
Patient perception of benefit†	28.3 (29.0)	37.8 (43.0)	.101	−9.5	−20.9, 1.9
Oswestry score	14.7 (14.0)	22.9 (22.0)	.004	−8.2	−13.6, −2.8
Lumbar mobility (cm)	14.0 (14.1)	14.2 (14.4)	.490	−0.2	−0.7, 0.3
Secondary outcome variables					
Maximal pain in the last 24 hours†	19.1 (13.0)	35.1 (26.0)	.012	−16.0	−28.3, −3.7
Pain severity relative to initial evaluation†	28.1 (24.0)	36.9 (44.0)	.143	−8.8	−20.6, 3.0
Pain with bending	1.1 (0)	2.5 (1.0)	.044	−1.4,	−2.7, 0
Pain with extension	1.3 (0)	2.9 (2.0)	.033	−1.6	−3.1, −0.1
Maximal tenderness on palpation†	19.0 (7.5)	21.9 (5.5)	.683	−2.9	−17.0, 11.2
Tenderness on palpation relative to initial evaluation†	29.7 (31.5)	31.0 (34.0)	.821	−1.3	−13.3, 10.6

Data represent means (medians).
* Two-sample *t* test with unequal variances.
† Visual analog scale (mm). Lower values indicate less pain.

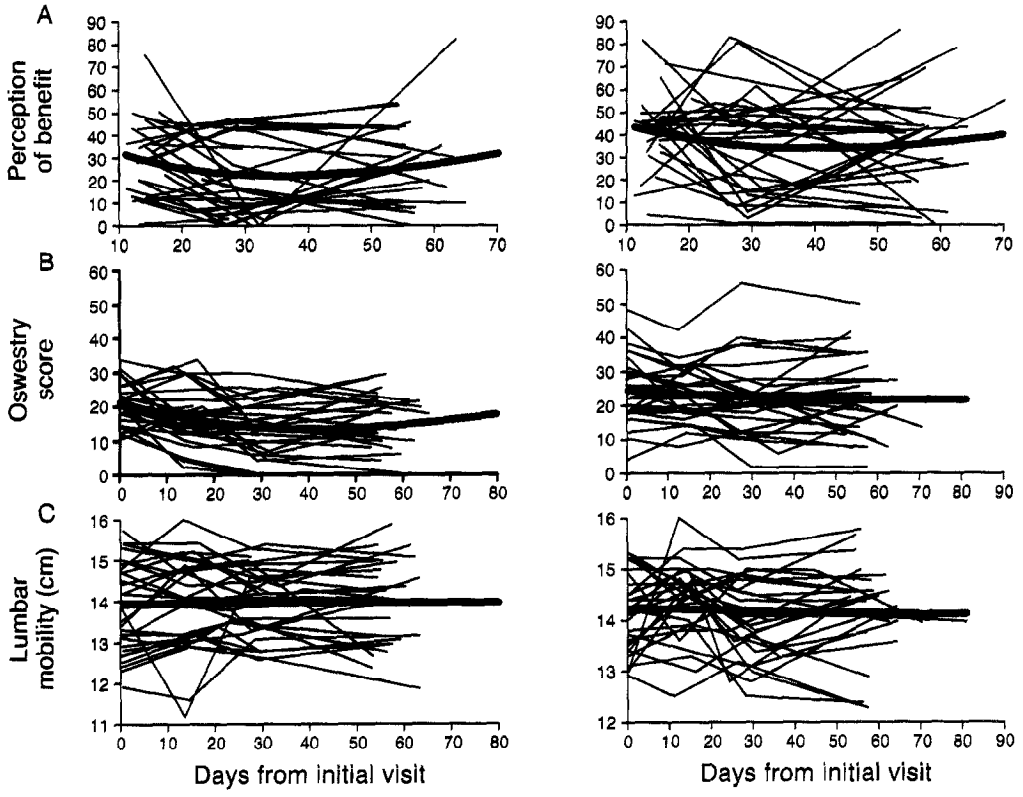

Fig 1. (A) Line diagrams comparing perception of treatment benefit among members of laser-treated (right diagram) and control (left diagram) groups. (B) Line diagrams comparing Oswestry Scores (lower scores indicate improved function) among members of laser-treated (right diagram) and control (left diagram) groups. (C) Line diagrams comparing lumbar mobility of members of laser-treated (right diagram) and control (left diagram) groups. Narrow lines represent individual subjects; heavy lines are a spline curve that indicates overall trend in each group.[26]

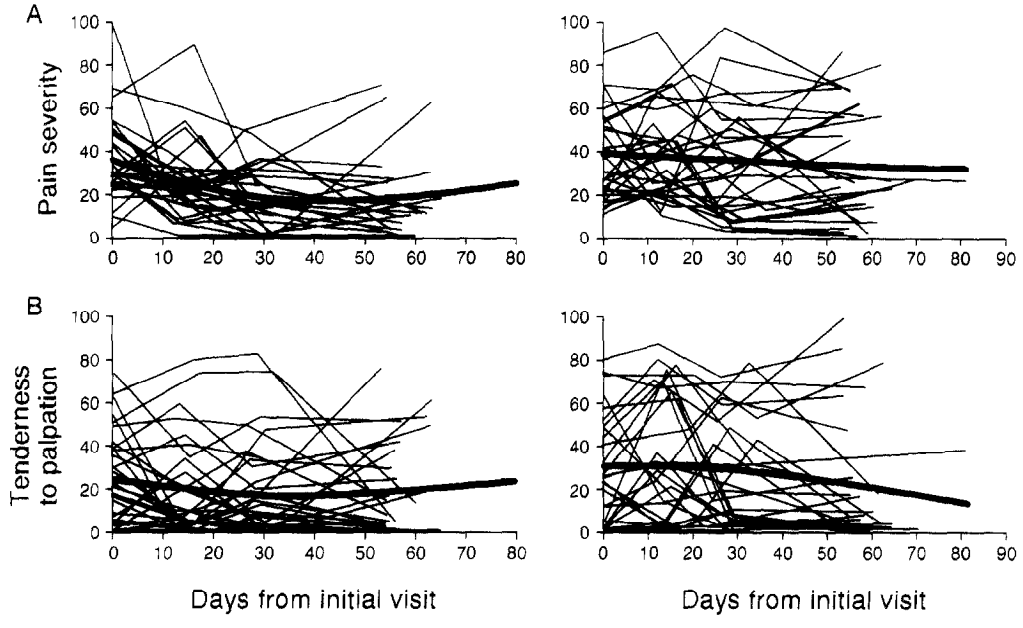

Fig 2. (A) Line diagrams comparing maximal pain reported in the previous 24 hours by members of laser-treated (right diagram) and control (left diagram) groups. (B) Line diagrams comparing maximal tenderness to palpation in members of laser-treated (right diagram) and control (left diagram) groups. Narrow lines represent the individual subjects; heavy lines are a spline curve that indicates overall trend in each group.[26]

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