A Randomized Controlled Evaluation of Low-Intensity Laser Therapy: Plantar Fasciitis

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ABSTRACT. Basford JR, Malanga GA, Krause DA, Harmsen WS. A randomized controlled evaluation of low-intensity laser therapy: plantar fasciitis. Arch Phys Med Rehabil 1998;79: 249-254.

Objective: To determine whether low-intensity laser irradiation, a widespread but controversial physical therapy agent, is an effective treatment of plantar fasciitis.

Design: A randomized, double-blinded, placebo-controlled clinical study.

Setting: A sports medicine clinic.

Subjects: Thirty-two otherwise healthy individuals with plantar fasciitis of more than 1 month's duration.

Intervention: Dummy or active irradiation with a 30mW .83μm GaAlAs continuous-wave infrared (IR) diode laser three times a week for 4 weeks.

Measurements: Morning pain, pain with toe walking, tenderness to palpation, windlass test response, medication consumption, and orthotic use were evaluated immediately before the study, as well as at the midpoint and end of treatment. Subjects were also evaluated at a follow-up 1 month after their last treatment.

Results: No significant differences were found between the groups in any of the outcome measures either during treatment or at the 1-month follow-up. Treatment, however, was well tolerated and side effects were minimal.

Conclusions: Low-intensity IR laser therapy appears safe but, at least within the parameters of this study, is not beneficial in the treatment of plantar fasciitis.

LOW-INTENSITY LASER therapy has gained popularity over the last 30 years as a safe, conservative, and effective way to treat a variety of soft tissue injuries and painful conditions. Initial work began in the eastern bloc countries in the mid-1960s.[1,2] This work, although often anecdotal, and sometimes more enthusiastic than scientific, initiated broader research and clinical interest. Over the years, clinical use has grown and investigational rigor has improved, although acceptance and scientific support remain mixed.[3] Today, low-power lasers are used in much of the world to accelerate wound healing, lessen pain, decrease inflammation, and speed recovery from musculoskeletal injury.[3] Despite this use, efficacy remains contentious and "laser therapy" has yet to gain Food and Drug Administration (FDA) approval for clinical use in the United States.[3]

The passage of time is improving our understanding of this modality. Today, several statements are possible. First, while treatment produces minimal temperature elevations (<0.5°C), laboratory investigations often find that laser radiation can alter cellular processes in a manner that is not explainable by heating alone.[3-6] Second, although the results of animal and human experiments are more mixed,[3,7-10] positive reports are common and clinical use has grown rapidly. Third, even though initial investigators used variety of lasers and irradiation parameters, most clinicians and researchers now use either infrared (IR) or helium-neon lasers with powers ranging from 10 to 90mW and treatment dosages of 1 to 4J/cm^2.[3] Fourth, light has an "action spectra" and specific wavelengths alter the activity of mitochondrial respiratory chains.[3,4,6,11] Finally, the visible red (.632μm) light of helium-neon laser irradiation penetrates tissue poorly, and it has been suggested that the more deeply penetrating radiation (.82 to .92μm) of the IR devices[12,13] provides the best compromise between biological effectiveness and penetration necessary to treat deeper musculoskeletal injuries.[3]

Because our current physical agents leave much to be desired, we chose to systematically study the potential benefits of this treatment approach. Since musculoskeletal injuries are probably the most common clinical application of laser therapy, we decided to investigate the effectiveness of a widely used IR laser on a frequent musculoskeletal complaint. In particular, we performed a double-blinded, randomized controlled clinical evaluation of the effectiveness of a 30mW .83μm gallium aluminum arsenide (GaAlAs) laser in the treatment of plantar fasciitis.

METHOD

This protocol was reviewed and approved by the Institutional Review Board of our institution. Following approval, 32 otherwise healthy individuals with the diagnosis of plantar fasciitis were recruited with announcements in our institutional newsletter and upon referral from sports medicine, orthopedic, and physical medicine clinics. Male and female volunteers met the study inclusion criteria if they were between the ages of 18 and 70 and had had plantar fasciitis of one or both feet for more than 30 days. Each of these individuals underwent a physical exam and history by a physician skilled in musculoskeletal medicine to rule out other musculoskeletal or neurologic causes for their pain. Diagnosis of plantar fasciitis depended on tenderness to pressure at the origin of the plantar fascia on the midanterior inferior border of the calcaneus as well as complaints of sharp, shooting, or localized inferior foot pain made worse with activity and/or upon arising in the morning. X-rays were not required but were reviewed if available. Specific efforts were made to avoid confusing cuboid syndrome pain, peroneus longus tendinitis, plantar nerve entrapment, and stress fractures with plantar fasciitis. All subjects were examined for foot mechanical dysfunction (eg, excessive pronation, pes cavus). Screening questions included "pain upon first walking

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after awakening," duration of pain, medication use, history of inflammatory, traumatic, or degenerative arthritis, or the existence of other medical problems. Exclusion criteria included treatment of the condition by a physician, physical therapist, or chiropractor within the last 30 days, a recent change in activity level, or the use of glucocorticoids for any reason. (Although we know of no established risk in pregnancy, women were required to be postmenopausal or practicing an effective means of birth control.) Foot orthotics, nonsteroidal anti-inflammatory drugs (NSAIDs), and simple analgesics were permitted, but their use was followed as an experimental variable. After a successful examination and history, the study participants were block-randomized into two groups. Each group was familiarized with the study design and received an identical introduction to plantar fasciitis and home treatment options by a blinded therapist.

Treatment was performed in a standard manner with the subjects washing their most symptomatic foot (chosen as the right if both feet were equally involved) in soap and water and the therapist lightly scrubbing the painful area with an alcohol swab. Both the therapist and the subject wore protective goggles during treatment and the foot was "irradiated" with a 30mW continuous-wave .83μm GaAlAs IR diode laser. Treatment consisted of 33 seconds of irradiation over the origin of the plantar fascia on the anterior inferior calcaneus and then two 33-second continuous sweeps of the laser along the prominent medial border of the plantar fascia. The sole difference between the groups was that a nonenergized probe was used for the control subjects. Treatments were given three times a week for 4 weeks. 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 the follow-up visit.

Evaluation was performed before the first treatment, as well as at the midpoint (sixth session) and at the end (12th session) of treatment. Subjects were seen again 28 to 35 days after the last treatment for a 1-month follow-up. Each evaluation was performed by one of two blinded physicians not involved in the treatment and consisted of repetition of the questions and examination given at the time of entrance into the study: pain on first steps in the morning, duration of pain, and effect of pain on daily activities. Subjects were also asked about medication use, activity level, side effects from treatment, and use of orthotics. Visual Analog Scale (VAS; 0mm = no pain, 1,000mm = incredibly severe pain) was used as much as possible to quantify subjective assessments. Examination was similar at each evaluation in that pain on palpation, toe walking, and windlass testing was graded. In addition, at the subsequent evaluations, subjects were asked to compare their pain and tenderness with that present initially. Evaluation at the last treatment and at follow-up included the above issues as well as questions about the subject's assessment of treatment effectiveness and group assignment.

Laser Characteristics and Calibration

The laser used in this study was a 30mW continuous-wave .83μm GaAlAs IR diode device[a] with a .03cm^2 spot size and an intensity of 955mW/cm^2. Treatments consisted of 1J/session at the calcaneal origin of the plantar fascia and 2J/session over the fascial arc (cumulative doses over the course of treatment were 12J at the fascial origin and 24J over the fascial band).

The laser was calibrated twice a week with a power meter incorporated in the unit. It was also calibrated at the beginning and end of the study with an external power meter. Power output remained stable at 27 ± 1mW.

Table 1: Demographics

Subject Characteristics	Control Group	Active Group	*p* Value
On feet most of day	71%	94%	NS*
Women	69%	88%	NS*
Age, median yr (range)	42 (33-51)	42.5 (26-64)	NS†
Symptom duration, median mo (range)	6.5 (0.5-90)	12.0 (3-180)	NS†
Foot treated (% right)	63%	56%	NS*
Current medication use	36%	38%	NS*
Current orthotic use	6%	0	NS*
Foot mechanics (normal %)	31%	62%	NS*

* Fisher's exact test.
† Rank sum Test.

Statistical Analysis

The responses for control and treatment groups were compared at individual points in time by using the rank sum test for continuous variables such as VAS variables. Fisher's exact test for an ordered outcome was used for the Windlass test results. Comparison of baseline state with final state was done using a matched analysis (rank sum test on the change scores). These form the main body of the results.

An overall model using all of the measurements for each subject was fit comparing the rate of improvement (change/time) between the treated and placebo groups in an attempt to increase the precision of the comparison. The generalized estimating equations (GEE) model was used to account for possible correlation in observations. Because the results did not differ between these two analyses, the results of the GEE model are not reported.

RESULTS

Thirty-one of the 32 subjects (16 irradiated, 15 controls) completed at least 11 of the 12 treatments and appeared for the evaluation sessions at the beginning, midpoint, and end of treatment. Twenty-eight patients (15 irradiated, 13 controls) completed at least 11 treatments and, in addition, returned for their 1-month (28 to 35 days) follow-up evaluation.

The demographics of the groups are outlined in table 1. The groups did not differ significantly and reflected the staff of our medical center in that the majority were women and on their feet throughout the day. Activity levels, as well as medication and orthotic use, were recorded at the first and all subsequent evaluations. These did not change significantly over the period of the study.

No significant differences were found over the period of the study between the groups in terms of pain severity in the morning, duration of painful walking upon arising, examination, or medication and orthotic use (tables 2-5, figs 1-3).

Table 2: Signs and Symptoms at Initial Evaluation

	Control Group	Active Group	Significance
Distance (m) walked in morning before stop limping, median (range)	7.5 (2-33)	7.5 (1-33)	NS†
Pain severity when first walked in morning*	466 (40-860)	579 (222-970)	NS†
Positive Windlass test (%)	63	75	NS‡

* VAS in millimeters, median (range).
† Rank sum Test.
‡ Exact ordered contingency table.

Table 3: Signs and Symptoms At Midpoint Evaluation

	Control Group	Active Group	Significance
Distance (m) walked in morning before stop limping, median (range)	6.7 (0-16.7)	5 (.8-33)	NS†
Pain severity when first walked in morning*	253 (135-790)	356 (112-680)	NS†
Pain on palpation (%)*	581 (31-890)	421 (60-9280)	NS†
Pain with palpation relative to start of treatment*	356 (160-639)	330 (0-610)	NS†
Pain on toe walking relative to start of treatment*	400 (90-450)	415 (20-470)	NS†
Positive Windlass test (%)	56	44	NS‡

* VAS in millimeters, median (range).
† Rank sum test.
‡ Exact ordered contingency table.

Blinding seemed to have been effective in that the subjects had about a chance probability of identifying their group assignment (table 6). Side effects were negligible, with 96% of the subjects noting no side effects and the remainder reporting only a mild sensation during or after treatment. The data presented in the tables represent the 28 subjects that completed the study and returned for the follow-up visit. Identical calculations, which included the individuals who did not complete the entire study and evaluation process, revealed no change in outcome.

DISCUSSION

We found that low-intensity laser therapy administered in accordance with our protocol is safe but is not beneficial in the treatment of plantar fasciitis. Since laser therapy is accepted in much of the world, however, a point-by-point discussion of the possible reasons for our findings may be helpful.

An obvious explanation for our negative findings is that laser therapy is not an effective treatment for any condition. This

Table 4: Signs and Symptoms at Last Treatment

	Control Group	Active Group	Significance
Distance (m) walked in morning before stop limping, median (range)	5 (0-15)	3 (0-33)	NS†
Pain severity when first walked in morning*	205 (30-690)	235 (90-720)	NS†
Pain on palpation*	350 (12-855)	320 (75-838)	NS†
Pain with toe walking*	180 (0-615)	18 (0-445)	.082†
Pain with palpation relative to start of treatment*	332 (45-580)	317 (41-720)	NS†
Pain on toe walking relative to start of treatment*	425 (180-565)	425 (0-467)	NS†
Positive Windlass test (%)	60	56	NS‡

* VAS in millimeters, median (range).
† Rank sum test.
‡ Exact ordered contingency table.

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

	Control Group	Active Group	Significance
Distance (m) walked in morning before stop limping, median (range)	15 (0-13)	5 (0-35)	0.1†
Pain severity when first walked in morning*	272 (120-205)	205 (0-855)	NS†
Pain on palpation*	355 (55-600)	390 (0-730)	NS†
Pain with toe walking*	100 (0-312)	12 (0-605)	NS†
Pain with palpation relative to start of treatment*	255 (168-668)	230 (18-660)	NS†
Pain on toe walking relative to start of treatment*	370 (170-430)	412 (122-660)	NS†
Positive Windlass test (%)	30	50	NS‡

* VAS in millimeters, median (range).
† Rank sum test.
‡ Exact ordered contingency table.

argument is potentially correct and is supported to some extent by the fact that some studies have found no benefit from treatment,[3] but ignores the persuasive evidence that laser irradiation at these intensities can alter cellular metabolism, protein synthesis, and immune response[4-6,11,15] and has been found to accelerate wound healing in many animal studies.[3,16] This argument also ignores clinical studies that have shown that laser therapy lessens pain[3,10] and accelerates the healing of several soft tissue conditions and neurologic injuries.[1,3,8,17]

Another possible explanation is that our design, technique, or subject selection was faulty. We do not believe this is true. Patient selection, randomization, treatment, and laser calibration were done in a careful and consistent manner by individuals familiar with musculoskeletal medicine and experienced in low-intensity laser therapy. The physician evaluators were experienced and excluded all subjects who did not clearly have plantar fasciitis. (In fact, most subjects had been previously diagnosed as having plantar fasciitis by other physicians before entry into our study.) The probes did not differ in temperature (due to the low energies involved in treatment) and blinding was further assured by the invisible nature of the IR beam. The relatively low incidence of orthotic and medication use represents not a lack of severity, but the chronicity of the subjects' conditions and their feelings that neither orthotics nor medication had provided much benefit.

It could be argued that the radiation was unable to penetrate deeply enough to treat the plantar fascia. This idea is not supported by the literature. This wavelength (.83μm) and power have been reported clinically effective for multiple musculoskeletal conditions at depths similar to those encountered in our study.[3] In addition, .83μm is within the IR spectrum and IR radiation penetrates tissue particularly well.[12,13]

It might be maintained that the wrong wavelength was chosen. We doubt this, as we chose a wavelength, and device, commonly used for these conditions. In addition, the consensus of many in the laser therapy community is that the IR wavelengths are the most effective choice for both theoretical (penetration) and empirical reasons.[12,13]

The correct dosage is a perennial argument. It should be noted that many investigators have reported significant laboratory and clinical effects using lasers with powers and treatment dosages of this magnitude or smaller.[1,2,4,11] Our study was a clinical study and the laser we evaluated is in common clinical use, with comparable irradiation parameters, as a treatment for

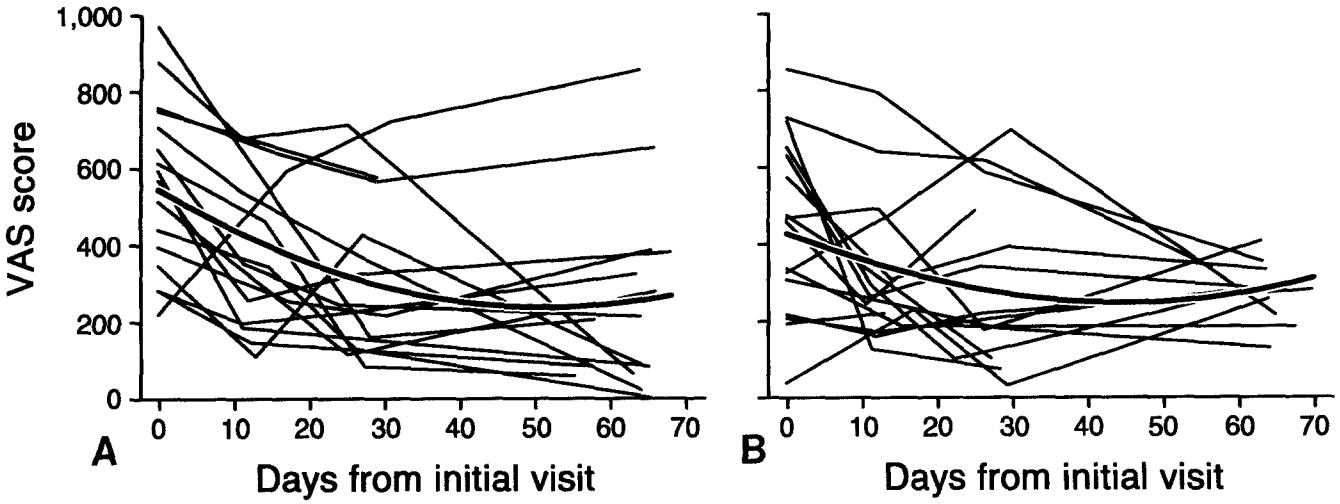

Fig 1. VAS line diagrams of pain severity during of the first walk of the morning for the (A) active and (B) control groups. VAS measurements ranged from 0mm (no pain) to 1,000mm (incredibly severe pain). The narrower lines represent the individual subjects; the broader lines represent the group means.

this and similar conditions.[10] Whether higher doses may be effective remains to be proven.

Another possibility is that the laser power and wavelength were appropriate, but that other parameters should be adjusted. This is another perennial argument. A myriad of choices are possible. We have already addressed wavelength and power issues. Another potential issue is pulse rate. It has been suggested that a pulsed laser beam is more effective than the

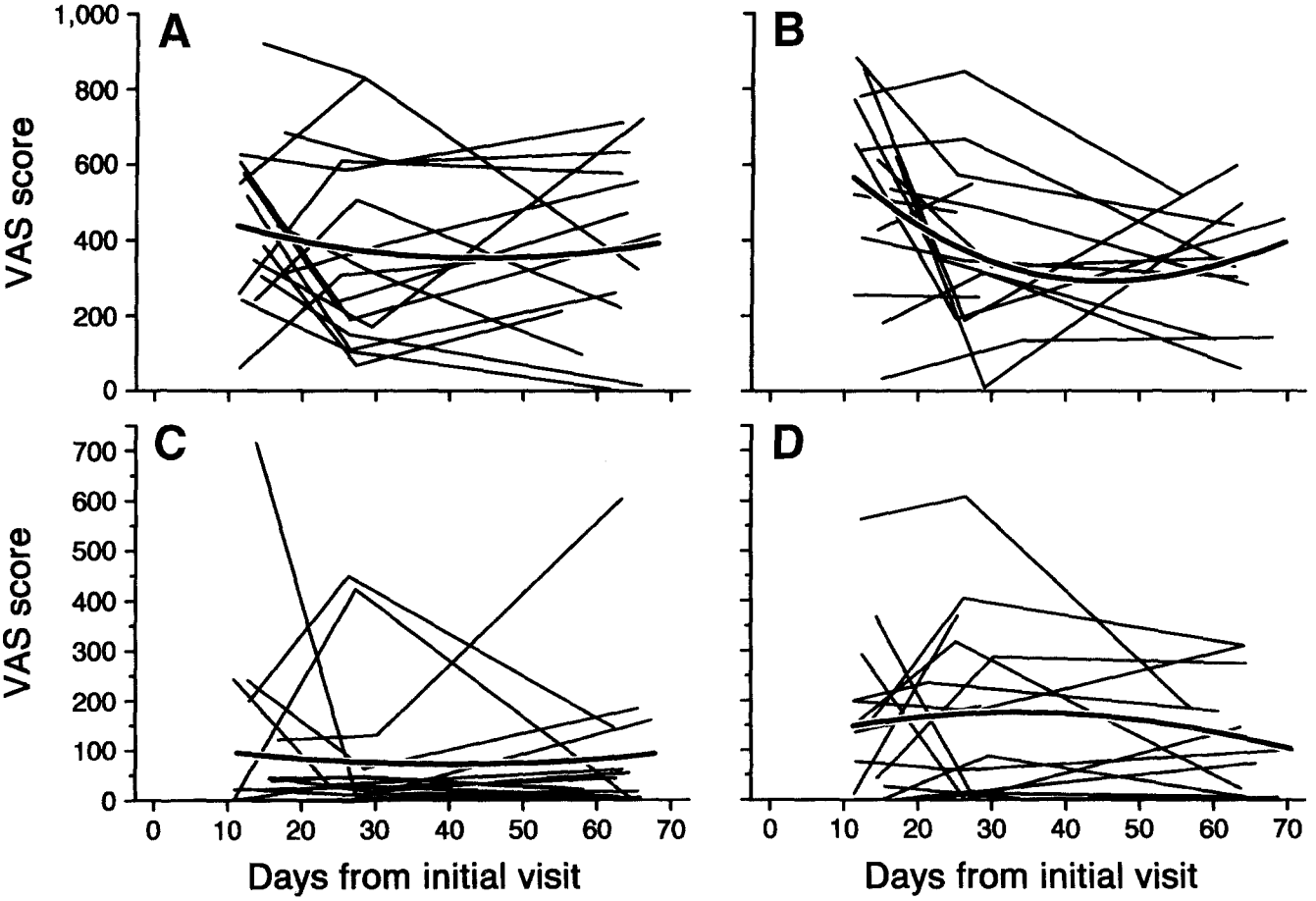

Fig 2. VAS line diagrams of pain on palpation for the (A) active and (B) control groups, and VAS line diagrams of the severity of pain on toe walking for the (C) active and (D) control groups. The narrower lines represent the individual subjects; the broader lines represent the group means.

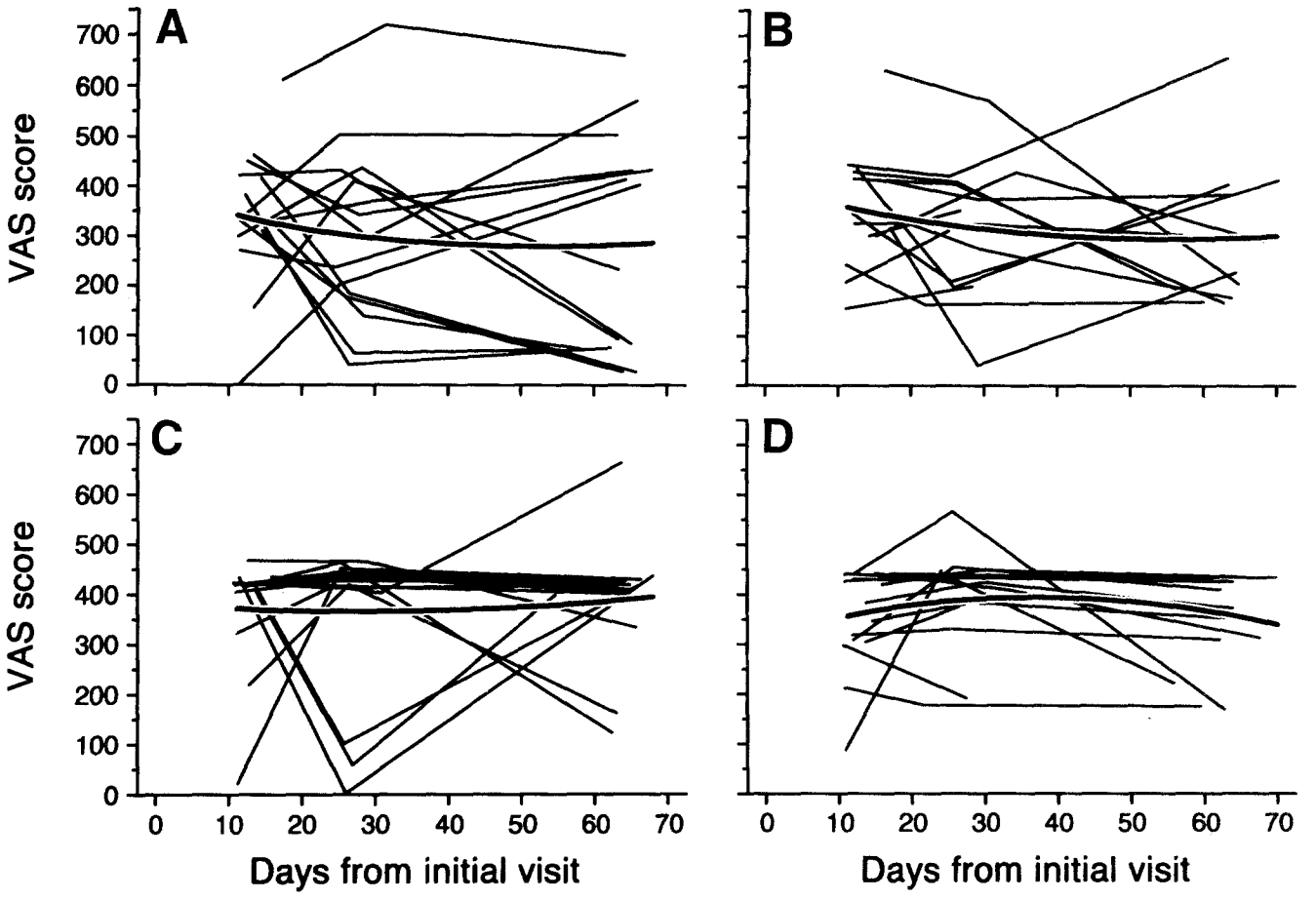

Fig 3. VAS line diagrams of the severity of pain on palpation for the (A) active and (B) control groups relative to the beginning of therapy, and VAS line diagrams of the severity of pain on toe walking for the (C) active and (D) control groups relative to the beginning of therapy at the evaluation. VAS measurements ranged from 0mm (no pain) to 500mm (no change) to 1,000mm (incredibly worse). The narrower lines represent the individual subjects; the broader lines represent the group means.

continuous-wave beam in our study. There is some support in the literature for this idea, but continuous-wave devices are in common use and many studies have found them effective.

A case might be made that plantar fasciitis might not be responsive to laser therapy. There are no *a priori* reasons to expect this. Plantar fasciitis is often recalcitrant to standard therapeutic or medical intervention, but we have no reason to expect that it should be particularly resistant to laser therapy.

In summary, we did not find .83μm continuous-wave IR laser radiation effective in the treatment of plantar fasciitis. It is possible that higher treatment intensities/energies or a different wave form might be effective, but we do not know. At this point, we believe that this modality warrants further study but is unestablished as a treatment of musculoskeletal disease.

Table 6: Subject Assessment of Group Assignment

	Control Group Assignment	Active Group Assignment	Cumulative
Subject believed he/she in control group	20%	27%	47%
Subject believed he/she in active group	30%	23%	53%

All nonsignificant (Fisher's exact test).

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