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Lateral Epicondylalgia: Report of Noneffective Midlaser Treatment

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ABSTRACT. Haker EHK, Lundeberg TCM. Lateral epicondylalgia: Report of noneffective midlaser treatment. Arch Phys Med Rehabil 1991;72:984–8.

• This study was carried out to explore the pain-alleviating effect of Ga-As + He-Ne laser (gallium-arsenide + helium-neon) in lateral epicondylalgia. A Space Mid Laser Mix 5-up laser was used. The probe consisted of five Ga-As emitters and one He-Ne emitter in the center. The parameters for Ga-As were wavelength, 904nm; average output power, 4mW, peak power, 10W; pulse frequency, 3800Hz; pulse duration, 180nsec; divergence, 70mrad. The He-Ne parameters were wavelength, 632.8nm; continous; power output, 5mW, divergence 60mrad. A pen laser (Ga-As) was also included in the equipment. Two machines were available; one of them had no output in the Ga-As diodes, and the He-Ne emitter was replaced with a red light emitter. Fifty-eight patients were consecutively assigned to two groups for laser or placebo. The probe was applied perpendicularly over the painful area for eight minutes, and then the pen probe was applied to two acupuncture points, LI 11 and LI 12, for two minutes per point. The treatments were given three to four times weekly, ten treatments in all. Follow-ups were done after 3, 6, and 12 months. The treatment procedure was performed exactly according to the manufacturer's manual for this diagnosis. No other therapeutic measures were used, and medication use was proscribed during the treatments and the follow-up period. The statistical analysis showed no significant differences in subjective or objective outcome between the laser and placebo treatments after the treatment period. However, the objective outcome indicated a difference in favor of the placebo treatment ($p < .06$). No differences were seen at follow-up at 3, 6, and 12 months. Our results do not support the use of Space Mid Laser Mix 5-up laser treatment with the chosen parameters in lateral epicondylalgia.

ect *KEY WORDS: Epicondylalgia; Tennis elbow; Ga-As laser; He-Ne laser; Pain; Placebo*

Tennis elbow, lateral humeral epicondylalgia[1,2] or "lateral elbow syndrome"[3] is a painful condition at the lateral aspect of the elbow. There is still no general agreement about the etiology, but it appears to be multifactorial in origin, and the clinical picture is often fairly uniform.[1,3-7]

Low-energy laser treatment is widely used in pain treatment by physicians, physiotherapists, and so-called laser therapists, despite contradictory experimental and clinical results.[8-16] Laser parameters used in these studies had the following ranges: wavelength, 780 to 904nm; pulse frequency, 50 to 80Hz (pulse train); peak power, 8.3 to 72W; average output, .07 to 12mW.

There is a wide variety of low-energy laser apparatus commercially available. One commonly used is Space Mid Laser Mix 5-up consisting of a probe with five Ga-As laser emitters and one He-Ne emitter in the center. The parameters for Ga-As are wavelength, 904nm; pulse duration, 180nsec; pulse frequency, 3,800Hz; peak power, 10W; average output power, 4mW. The He-Ne parameters are wavelength, 632.8nm; continous; power output, 5mW; divergence, 70mrad. A pen laser (Ga-As) is also included. The He-Ne emitter radiates a visible red light which is used to direct the invisible Ga-As laser radiation.

Whether low-power He-Ne laser radiation has a pain-relieving effect has been studied and refuted by Waylonis.[17] When a new approach is introduced into medical practice, it should prove beneficial and, ideally, either be better than or at least equal in efficacy to alternative methods. The purpose of our present study was to explore whether treatment with Space Mid Laser Mix 5-up had a pain relieving effect in lateral epicondylalgia.

SUBJECTS

Seventy-four patients with lateral elbow pain were examined and evaluated at the clinic during six months. The patients were either selfreferred or referred by their physicians or physiotherapists.

Subjects were included if they had pain over the lateral epicondyle at two or more of four tests and pain for at least one month. The diagnostic criteria used were (1) Palpation of the lateral epicondyle. (2) Resisted wrist extension. Position: shoulder flexion, 60°, elbow extended (not supported); forearm pronated; wrist extended about 30°. Pressure was applied on the dorsum of the second and third metacarpal bones in the direction of flexion toward the ulnar side to prove involvement of the extensor carpi radialis brevis and longus (fig 1).[3] Passive stretching of the extensor muscle group. Position: elbow extended, forearm pronated, maximal wrist palmar flexion. (4) Resisted finger extension. Position: 60° of shoulder flexion, elbow extended, forearm pronated, fingers extended. Resisted extension was applied manually on digiti II to V to prove involvement of the extensor indicis, the extensor digitorum,

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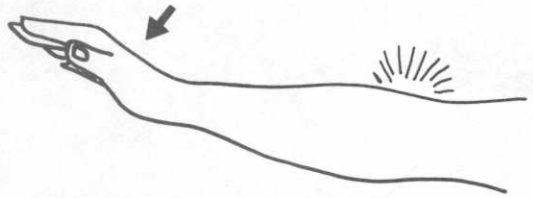

Fig 1—Test 2. Resisted wrist extension.

and the extensor digiti minimi. Resistance applied on digitus III was the middle-finger test (fig 2).

Patients were excluded who demonstrated the following: (1) dysfunction in the shoulder, neck, and/or thoracic region; (2) local arthritis or generalized polyarthritis; (3) neurologic abnormality; and (4) radial nerve entrapment.[18,19]

Sixty patients met the criteria of lateral epicondylalgia, and they were consecutively assigned at random to two groups. Two patients dropped out during the treatment period for one was on medication without our knowledge; the other wanted to try a different mode of treatment because of continuing elbow pain after six treatments. Fifty-eight patients (43 men and 15 women) completed the study; they were all limited to unilateral epicondylalgia.

Group A, the laser group, had 29 patients (18 men and 11 women) with a mean age of 45.6 years (range = 34 to 57 years), and a median duration of pain of seven months (range = 1 to 60 months).

Group B, the placebo group, had 29 patients (25 men and four women) with a mean age of 45 years (range = 33 to 65 years), and a median duration of pain of four months (range = 1 to 24 months).

Details were recorded for profession, onset of pain, pain at night, pain at rest, character of pain (dull or shooting), time of sick listing, workload and involvement in monotonous and repetitive movements. Furthermore, they were asked about activities worsening the pain (ie, brushing teeth, shaking hands, grasping, and lifting) and rotatory movements of the arm (ie, using a screwdriver, knitting, handwriting, driving a car, and flexion and/or extension of the elbow). Affected arm, cause of pain, and previous treatment are presented in table 1.

All patients were informed that two modes of radiation treatment were to be tried out and that no fee was to be charged. No other treatments or drugs were to be used during the month before the trials began and throughout the study. They were instructed to "use the arm, but avoid painful movements." The study was approved by the ethical committee at Karolinska Institutet.

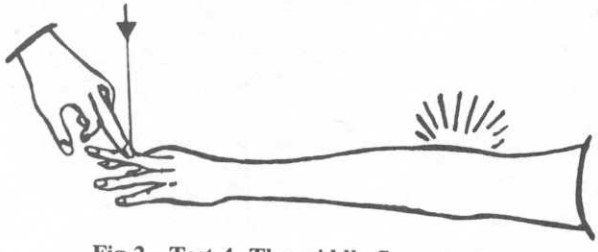

Fig 2—Test 4. The middle finger test.

Table 1: Affected Arm, Cause, and Previous Treatments

	Laser group (n)	Placebo group (n)
Total patients	29	29
Affected arm - right	23	25
Dominant arm - right	28	29
Work	12	11
Sport	8	13
Other activities	11	8
Unknown	3	1
Steroids*	13	8
NSAID +	5	5
Ultrasound	4	5
Other treatments	11	13
Untreated	12	13

*Steroids from local injection; NSAID + = nonsteroid anti-inflammatory drug

METHODS

The Space Mid Laser Mix 5-up, as described earlier, was used. The probe was used to radiate the area over the epicondyle for eight minutes; then the pen laser was used to radiate two points corresponding to the acupuncture points LI 11 and LI 12 for two minutes per point. Both the laser probe (fig) and the pen laser were applied perpendicularly.

Two machines were available. One of them had no output in the Ga-As emitters; the He-Ne laser emitter had been replaced with a red light emitter. No difference in the machines' appearance was observed either by the assistant who carried out the treatments or by any other persons involved in the study. The output of the laser machine was controlled and measured every other week. The laser and placebo code was broken only after the follow-ups.

The patients were treated singly to avoid influencing one another. They were treated three or four times weekly, and given ten treatments in all. Follow-ups were done after 3, 6, and 12 months.

EVALUATION

One of the authors, not aware of the treatment schedule, examined the patients before and after the treatment period and at the follow-ups after 3, 6, and 12 months. In addition

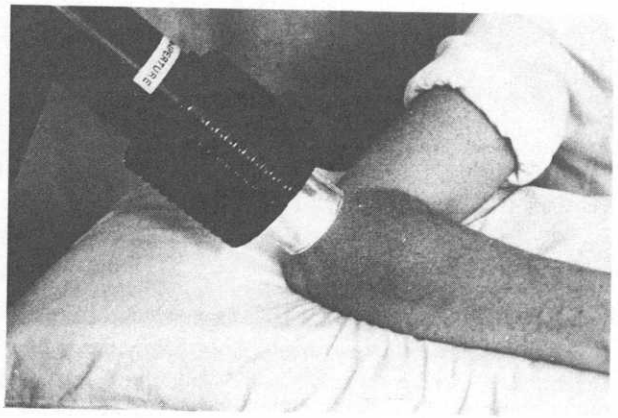

Fig 3—Application of the laser probe.

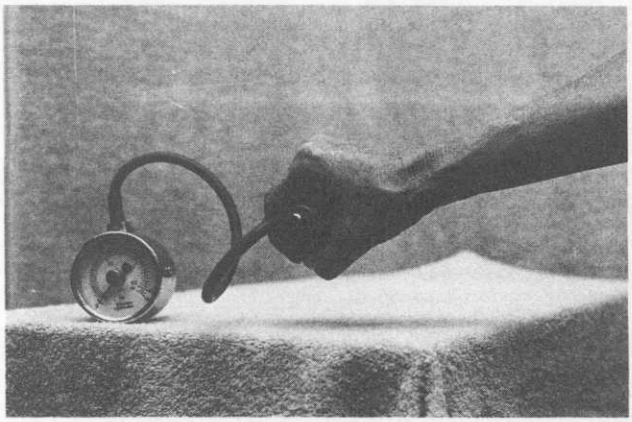

Fig 4—Test position of the Martin vigorimeter.

to the four diagnostic criteria (***tests 1 to 4***), the patients were evaluated in another four tests.

In tests 5 and 6, the patients were tested as to whether pain could be produced at the lateral aspect of the epicondyle by isometric pronation and supination of the forearm. The test position was elbow flexed 90 degrees and supported with the forearm between pronation and supination.

In the vigorimeter test, test 7, grip strength was measured. Thorngren and Werner[20] used the Martin vigorimeter to determine the ratio dominant to the nondominant hand to $1.07 \pm .11$. According to this result, the value of the nonaffected arm can serve as a parameter in evaluating the pain-free grip strength. The vigorimeter is a dynamometer with a rubber balloon which is compressed in the hand. The air-pressure within the balloon is registered in kilopond per square centimeter ($1kp/cm^2 = 98.1kPa$) on a manometer by means of a rubber tube connection. In our study, a medium sized balloon was used.

The patient was seated comfortably, shoulder 60° in between flexion and abduction, elbow extended, forearm pronated with 20° dorsiflexion of the wrist, holding the balloon with the connection tube protruding between thumb and index finger. The patients were instructed to squeeze the balloon and to stop pressure when any kind of pain was experienced over the lateral epicondyle (fig 4).

The reading was not visible to the patient. If the mere position of the arm caused pain, this was noted as zero, and no pressure was exerted. Otherwise, the mean value of three consecutive estimations was calculated in kPa. The pain threshold when gripping was noted before and after the ten treatments and at the follow-ups. The posttreatment values were compared to those obtained at the pretreatment evaluation, and the median values of the differences were calculated.

Test 8 was the lifting test. Sitting in the position described above, the patient was also required to lift four different weights, 1kg, 2kg, 3kg, and 4kg, with grip diameters of 2.5 to 3cm. Pain over the epicondyle was recorded as present or absent. All the tests were performed bilaterally, and the number of patients positive at the different tests is presented in table 2.

After the tenth treatment and at the follow-ups all eight clinical tests were repeated, and, moreover, a subjective assessment completed the clinical examination.

A scale of 1 to 5 was shown to the patients, indicating: 1 = excellent, 2 = good, 3 = improved, 4 = slightly improved, and 5 = unchanged or worse. They were asked, "How do you assess your pain today compared to the pretreatment condition?" The patients indicated the score that most adequately reflected their present condition.

Table 2: Test Schedule and Pretreatment Values

		Number of patients (total = 58)
1.	Pain at epicondyle	58
2.	Resisted wrist extension	54
3.	Stretching the extensor muscle	12
4.	Middle-finger test	52
5.	Resisted pronation	33
6.	Resisted supination	33
7.	Vigorimeter test	57
8.	Lifting test (1,2,3, and 4 kg)	18,38,46,49

The number of patients denotes how many were positive at the different clinical tests performed before the first treatment.

Correlation analysis, the Mann-Whitney U-test of two independent samples, and chi-square test were used for the statistical analyses.

RESULTS

Fifty-eight patients completed the study. At the three month follow-up, two patients in the laser group and four in the placebo group had withdrawn due to insufficient pain alleviation and had changed to other modes of treatment. Another four patients in the laser group and another six in the placebo group had withdrawn at the six month follow-up. Totally, 17 patients had withdrawn after 12 months, six in the laser group and 11 in the placebo group.

The subjective and objective outcomes did not show any significant difference between the groups after ten treatments. However, the objective outcome (the vigorimeter test) did show a difference ($p < .06$) between the groups favoring the placebo treatment. No differences were observed between the groups at the follow-ups (fig 5, table 3).

The patients in the two groups had similar pretreatment conditions. There was no significant difference between the groups in relation to profession, onset of pain, pain at night, pain at rest, character of pain, time of sick listing, workload, involvement in monotonous and repetitive movements, activities worsening the pain, affected arm, cause, and previous treatment. A difference was seen in relation to gender distribution ($p < .06$). There was no correlation between the preduration of pain or any of the other observed parameters, and the increase of the pain-free grip (vigorimeter test). No side effects were reported during or after the treatment period.

DISCUSSION

In this study no significant differences could be observed between the laser and placebo groups after the treatment period or at the follow-ups. In three previous double-blind studies, using Ga-As laser, we tried different modes and doses in the treatment of lateral epicondylalgia. In the first two studies,[12,13] acupuncture points related to the elbow were radiated, whereas the painful area was radiated in the third study (unpublished observation). The dose of treatment was .004J/point (.07mW,

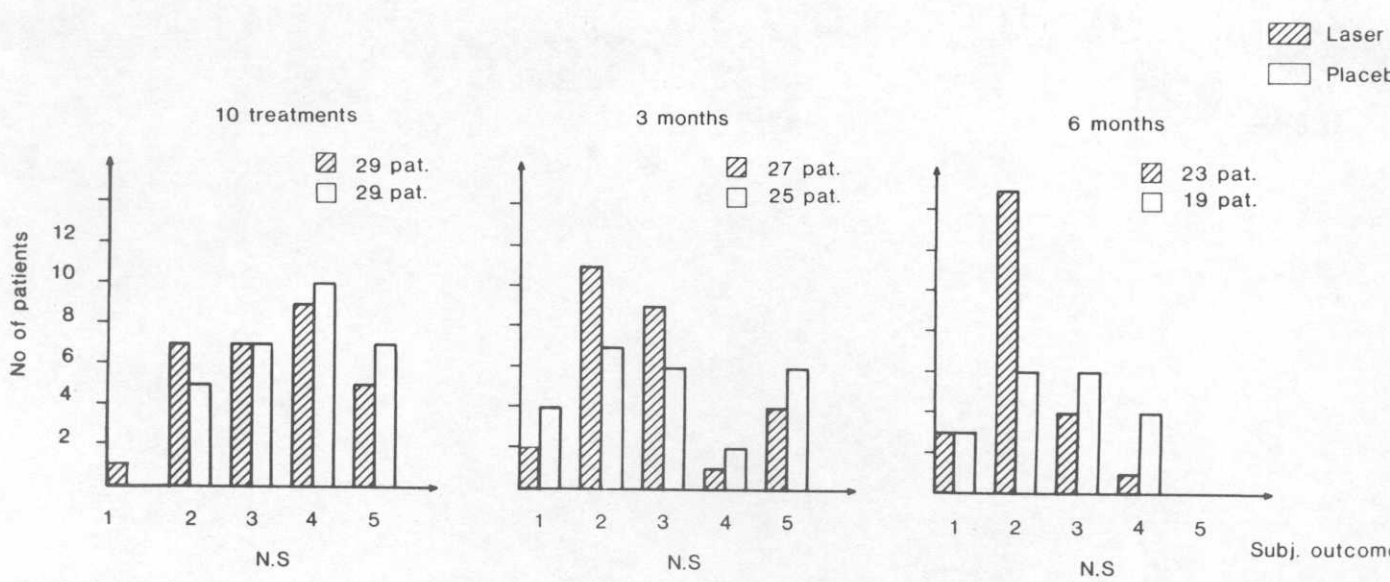

Fig 5—Subjective outcome after 10 treatments, 3, 6, and 12 months. 1 = excellent, 2 = good, 3 = improved, 4 = slightly improved, and 5 = unchanged/worse. NS = non significant.

60sec, 10 points, 73Hz pulse train) in the first study[13] and .36J/point (12mW, 30sec, 5 points, 70Hz pulse train) in the second[12] and third studies.

No differences between the laser and placebo groups could be reported in the first two studies. When radiating the painful area, a significant difference was found between the laser and placebo groups regarding the objective outcome favoring the laser treatment, although no corresponding difference was seen in the subjective outcome. These results indicated that Ga-As laser treatment might be beneficial when applied locally with a treatment dose of .36J/point (12mW, 30sec).

However, in spite of an increased dose of Ga-As treatment, 1.92J/point (4mW, eight minutes) in the present study, no significant difference was found between the laser and placebo groups in relation to the subjective or objective outcome. There was a difference in the increase of the pain-free grip strength in favor of the placebo treatment ($p < .06$). Changing dose by reducing the average power output and increasing the time of treatment does not seem to be the key to using the Ga-As laser.

In 1989 England and associates[10] presented a study in which 30 patients were allocated at random to Ga-As laser therapy, placebo laser, or drug therapy in the treatment of supraspinatus and bicipital tendinitis. A pen laser was used, with a treatment dose of 0.9J/diod, one diod (904nm, 4,000Hz, 3mW, five mintues). The diganostic criteria were well described, and the laser emitter was applied in a way similar to this study. The point of maximum tenderness was treated three times a week for a period of two weeks. The Ga-As laser treatment was found to be significantly better than placebo. However, the limited number of patients treated, ten in each group, reduces the value of the results obtained.

In a study by Meier and Kerkour,[15] the Space Mid Laser Mix 5-up (Ga-As + He-Ne) treatment was compared to He-Ne laser in patellar and Achilles tendinitis. A significant difference was seen in the patients with Achilles tendinitis after the treatment period, favoring Ga-As + He-Ne laser treatment. No corresponding difference was seen in the patients suffering from patellar tendinitis.[15] Even though the results are interesting, the inadequate presentation of the results and the statistical methods used make it difficult to draw any conclusions from the study.

Table 3: Evaluation of the Vigorimeter Test (kPa)*

	Pretreatment	After 10 treatments	3 months	6 months	12 months
Laser	30	0	28	40	52
Placebo	26	16	32	44	61
	NS	NS	NS	NS	NS

* Differences between posttreatment and pretreatment values were calculated after ten treatments, and at 3, 6, and 12 months. The median values of the differences obtained were compared between the laser and placebo groups. NS = nonsignificant.

CONCLUSION

Studies comparing the effects of Ga-As laser and placebo have often been carried out with nonhomogeneous groups of patients.[10,15] Different lasers may have different effectiveness in different diagnoses[21] and consequently, clinical studies carried out elucidating the effect of laser treatment should be performed with strict diagnostic criteria and a detailed description of material and methods. The result of this study does not support the use of Space Mid Laser Mix 5-up (Ga-As + He-Ne) in the treatment of lateral epicondylalgia.

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