Original Article

Is Low-Energy Laser Treatment Effective in Lateral Epicondylalgia?

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Abstract
The aim of this double-blind study was to explore the pain-alleviating effect of low energy laser in lateral epicondylalgia. Forty-nine patients were consecutively assigned at random to two groups, laser or placebo. The Mid 1500 Irradia laser was used with the following parameters: wavelength 904 nm; average power output 12 mW; peak value 8.3 W; frequency 70 Hz (pulse train 8000 Hz). The laser (Ga-As) was locally applied to 6 sites on and around the epicondyle. Each point was treated for 30 sec, resulting in a dose of 0.36 J/point and an area of treatment of 0.2 mm². Patients were treated 2–3 times weekly, for a total of 10 treatments. Follow-ups were done after three and 12 mo. The statistical analysis showed that the laser treated group had a significant improvement in some objective outcomes after the treatment period and at the 3 mo follow-up, but there were no significant differences in the subjective outcomes between the groups. Irradia laser treatment may be a valuable therapy in lateral epicondylalgia, if carried out as described in this study. However, further studies are necessary before low energy laser can be employed as a pain-relieving method. J Pain Symptom Manage 1991;6:241–246.

Key Words
Ga-As laser, epicondylalgia, pain, placebo, tennis elbow

Introduction
Tennis elbow or lateral epicondylalgia1,2 is a common painful syndrome at the lateral aspect of the elbow. There is no agreement about the underlying pathology, but the clinical picture is fairly uniform.3–7

During the past few years, great interest has been focused on low energy laser in pain treatment. The utility of the method has been disputed due to contradictory experimental and clinical results,8–17 but still it has become widely used.

In two previous double-blind studies performed in patients with lateral epicondylalgia,15,16 we evaluated the pain-relieving effect of different dosages of Ga-As laser (either 0.004 or 0.36 J/point) applied to acupuncture points related to the elbow and observed no differences between the laser group and the placebo group. In the present study, we used same laser and dose as the second study,14 but applied the treatment to the painful area over the epicondyle to explore the effect of local therapy on the pain of this condition.
Patients and Methods

Patients

The study was approved by the ethical committee at the Karolinska Institute. Sixty-three patients suffering from lateral elbow pain were examined and evaluated at the clinic during a period of one year. The patients were either self-referred or referred by their physician or physiotherapist. Patients were recruited for the study if pain was experienced for more than 1 month over the lateral epicondyle and could be produced by two or more of the following four tests:

Test 1: Palpation of the lateral epicondyle.

Test 2: Resisted wrist extension. Position: shoulder flexion 60°, elbow extended (not supported), forearm pronated, wrist extended about 30°. Pressure is applied to the dorsum of the second and third metacarpal bones in the direction of flexion toward the ulnar side to prove involvement of ext. carpi radialis brevis and longus (Figure 1).


Test 4: Resisted finger extension. Position: 60° of shoulder flexion, elbow extended, forearm pronated, fingers extended. Resisted extension was applied manually to digits II-V to prove involvement of the ext. indicis, the ext. digiti minimi and ext. digitum. Resistance applied to digit III = middle finger test (Figure 2).

The patients who were excluded from the study were suffering from: 1) Dysfunction in the shoulder, neck and/or thoracic region; 2) Local arthritis, generalized polyarthritis; 3) Neurologic abnormalities; 4) Radial nerve entrapment.18,19

Fifty-two patients met the criteria of lateral epicondylalgia. One patient in the laser group and two patients in the placebo group “dropped out” during the first wk without providing a reason. Forty-nine patients completed the study.

Affected arm, cause of pain and previous treatment are presented in Table 1. Details were also recorded about profession, work load, involvement in monotonous and repetitive movements, onset of pain, pain at rest, pain at night, character of pain and time of sick-listing.

All the 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 used during the month before the trials began or during the study period. Patients were instructed to “use the arm but avoid painful movements.”

Consecutive cases were randomly assigned to two groups:

Group A. The laser group: 25 patients, 17

<table>
<thead>
<tr>
<th>Affected arm, cause and previous treatments</th>
</tr>
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<tbody>
<tr>
<td>Group</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>Number of patients</td>
</tr>
<tr>
<td>Affected arm—right</td>
</tr>
<tr>
<td>Dom. arm—right</td>
</tr>
<tr>
<td>Cause</td>
</tr>
<tr>
<td>Work</td>
</tr>
<tr>
<td>Sport</td>
</tr>
<tr>
<td>Other activities</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td>Previous treatment</td>
</tr>
<tr>
<td>Steroids</td>
</tr>
<tr>
<td>Ultrasound</td>
</tr>
<tr>
<td>Other treatments</td>
</tr>
<tr>
<td>Untreated</td>
</tr>
</tbody>
</table>

A = The laser group; B = The placebo group.
men and 8 women, with a mean age of 45.6 yr (28–66) and a median duration of pain of 12 mo (1–35).

Group B. The placebo group: 24 patients, 14 men and 10 women, with a mean age of 43.3 yr (22–61) and a median duration of pain of 7 mo (1–60).

**Method of Treatment**

The Mid 1500 Irradia laser was used. This is a Ga-As laser, which produces a wavelength of 904 nm, a pulse duration of 180 ns, a measured average power output of 12 mW, a peak value of 8.3 W, and a frequency of 70 Hz (for pulse trains, each with a frequency of 8000 Hz). The laser was applied to 1 point at the anterior aspect of the lateral epicondyle and 5 points around this site at a radius of 1.5–2 cm. Each point was treated for 30 sec 2–3 times weekly, for 10 treatments in all. For each treatment, the laser wand was held perpendicularly 1 mm from the patient's skin, and the distance between skin and laser wand was maintained by means of a piece of plastic (5x5 mm) fixed to the wand (Figure 3).

The laser machine was standardized initially and then every month. An on/off key, marked A/B, was introduced into the transducer circuit and allowed mock radiation to be given to the placebo group without affecting the normal output when the key was turned on. The laser/placebo code was only broken after the patient follow-ups. An assistant, who was not aware of what A and B symbolized, carried out the treatments. Both groups were treated under the same conditions and the patients were treated singly to avoid influencing one another. Follow-ups were done at the clinic after three and 12 mo.

![Application of the laser](image)

**Method of Evaluation**

One of the authors, E.H., who was not aware of the treatment schedule, examined the patients before and after the treatment period and at the follow-ups 3 and 12 mo later.

The evaluation comprised the same four diagnostic tests that determined entry into the study and four additional tests as follows:

**Test 1-4**: Described previously.

**Test 5**: Patients were asked if pain could be produced by isometric pronation of the forearm. Test position: elbow flexed 90° and supported, forearm in-between pronation and supination.

**Test 6**: Patients were asked if pain could be produced at the lateral aspect of the epicondyle by isometric supination of the forearm. Test position: elbow flexed 90° and supported, forearm in between pronation and supination.

**Test 7**: The Vigotimeter test. The vigorimeter is a dynamometer with a rubber balloon that is compressed by the hand and is used to measure grip strength. The air pressure within the balloon is registered in kilopounds per square centimeter (1 kp/cm², 98.1 kPa) on a manometer by means of a rubber tube connection. In our study, a medium sized balloon was used. Thomsen and Werner²⁹ used the Martin vigorimeter to determine that the ratio of grip strength between the dominant and nondominant hand is 1.07 ± 0.11. Applying this result, the value of the nonaffected arm can serve as a parameter in evaluating pain-free grip strength. Consequently, we used the Martin vigorimeter to measure the grip strength in the nonaffected arm and the grip strength at pain threshold in the affected arm.

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 patient was instructed to squeeze the balloon and to stop pressure when any kind of pain was experienced over the lateral epicondyle. This was considered to be a positive vigorimeter test (Figure 4). It was not possible for the patient to observe the readings. If the mere position of the arm caused such
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 on gripping was noted before and after the 10 treatments and at follow-ups. The posttreatment values were compared to those obtained at the pretreatment evaluation and then the median values of the differences were calculated.

**Test 8: Lifting test.** Sitting in the position described above, the patient was also required to lift four different weights (1, 2, 3, and 4 kg), and pain over the epicondyle was recorded as present or absent.

All the tests were performed bilaterally.

After the tenth treatment and at follow-ups, all 8 clinical tests were repeated and a subjective assessment was made. Patients were asked, "How do you assess your pain today compared to the pretreatment condition?" Patients answered on a 1–5 scale, indicating: 1 = excellent, 2 = good, 3 = improved, 4 = slightly improved, and 5 = unchanged/worse.

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

**Results**

Forty-nine patients completed the study. Because of still existing elbow pain, two patients in each group withdrew after the tenth treatment; another 4 in the laser group and 6 in the placebo group withdrew after 3 mo. The number of patients with positive results on the tests prior to treatment is recorded in Table 2.

**Table 2**


*The number of patients indicates how many tested positive.

| Number of patients testing positive with 1, 2, 3, & 4 kg respectively. |

**Objective Outcome**

After 10 treatments and at the 3 mo follow-up, the pain threshold on gripping the balloon had significantly increased in the laser group compared to the placebo group (Table 3). The outcome of the 3 and 4 kg lifting test changed favorably after 10 treatments in the laser group, while the outcome of the 5 kg lifting test also changed favorably at the 3 mo follow-up.

Significantly fewer patients in the laser group reported pain at the middle finger test after 10 treatments (Table 4).

**Subjective Outcome**

The subjective outcome did not show any significant difference between the groups (Table 4).

**Table 3**

<table>
<thead>
<tr>
<th>Objective Outcome. Evaluation of the Vigorimeter Test (kPa)</th>
<th>10 Pretreatment Treatments 3 mo 1 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Laser 38</td>
<td>25</td>
</tr>
<tr>
<td>B Placebo 39</td>
<td>0</td>
</tr>
<tr>
<td>NS</td>
<td></td>
</tr>
</tbody>
</table>

Pretreat = The median values of the Vigorimeter test of the two groups were calculated before the first treatment. Because of the wide range, the median values were used.

The differences between the posttreatment and the pretreatment values were calculated after 10 treatments, 3 and 12 mo. The median values of the differences obtained were compared between the laser and the placebo group. NS = nonsignificant.
Table 4
Summary of Results

<table>
<thead>
<tr>
<th></th>
<th>10 Treatments</th>
<th>3 mo</th>
<th>1 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middle finger test</td>
<td>$p &lt; 0.05$</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Lifting 3 kg</td>
<td>$p &lt; 0.01$</td>
<td>$p &lt; 0.05$</td>
<td>NS</td>
</tr>
<tr>
<td>Lifting 4 kg</td>
<td>$p &lt; 0.01$</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Vigorimeter test</td>
<td>$p &lt; 0.01$</td>
<td>$p &lt; 0.01$</td>
<td>NS</td>
</tr>
<tr>
<td>Subjective outcome</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

Outcome of laser group after 10 treatments, and after 3 and 12 mo follow-up tests. The outcome favors the laser. NS = nonsignificant.

A good correlation was observed after 10 treatments and at the 3 mo follow-up in both groups between the subjective and the objective outcomes ($r = 0.70$ after 10 treatments and $r = 0.63$ after 3 mo in the laser group and $r = 0.66$ after 10 treatments and $r = 0.67$ after 3 mo in the placebo group).

Members of the two groups had a similar pretreatment condition. No correlation between the pretreatment duration of pain or any of the other observed parameters and the increase of the pain-free grip (Vigorimeter test) could be detected. No side effects were reported during or after the treatment period.

Discussion

The present study shows that patients suffering from lateral epicondylalgia who were treated with Irradia laser obtained a more significant improvement in objective measurements than patients treated with placebo laser. No difference was seen between the groups in subjective outcome. This lack of difference in the subjective outcome may indicate that a 5-point scale is not sensitive enough to detect minor changes. Even though there was no significant improvement of the subjective scale, there was a good correlation ($r = 0.70$) between the subjective and objective outcome.

Given the controlled nature of this trial, the results provide strong evidence for a true therapeutic effect of Ga-As laser. If so, low energy laser may have different effectiveness in different situations; frequency, dosage, technique, and tissue must be taken into account.

The mechanism of analgesia produced by low energy laser is unknown. Stimulation or inhibition of afferent nerves have been discussed, but there is no evidence to support these effects. Low energy laser does not produce changes in tissue temperature, and, for that reason, thermal mechanisms cannot explain the effect of laser irradiation. Likewise, it is unlikely that low energy laser provides local heating of mitochondria and other cell structures, thereby altering metabolic processes. The fact that laser is a form of electromagnetic energy and so may affect electric gradients across cell membranes has been considered but this hypothesis has been refuted.

It is plausible that laser induces nontermal photobiologic reactions, but it has not been settled whether these effects are specific to laser or may also be produced with nontermal light sources.

Low energy laser may be a valuable therapy in lateral epicondylalgia if carried out as described. However, our previous and present results indicate that further studies are needed to elucidate the pain-alleviating effect of low energy laser (Ga-As). More information is needed about the local effects of this treatment and the results produced by higher doses.

Acknowledgements

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References