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LOW LEVEL LASER VERSUS PLACEBO IN THE TREATMENT OF TENNIS ELBOW

Ottar Vasseljen Jr,[1] Nils Høeg,[2] Berit Kjeldstad,[3] Anders Johnsson[3] and Stig Larsen[4]

From the [1]Trondheim Fysikalske Institutt, Sverres gt. 3, 7045, Trondheim, [2]Orkanger Fysikalske Institutt, 7300 Orkanger, [3]Department of Physics, AVH, University of Trondheim, N-7055 Dragvoll and [4]Medstat, P.b. 37, N-2011 Strømmen, Norway

ABSTRACT. The effect of low level laser (GaAs) on lateral epicondylitis was investigated in a double-blind, randomized, controlled study. Thirty patients were assigned equally to a laser ($n=15$) or a placebo laser ($n=15$) group. All patients received eight treatments and were evaluated subjectively and objectively before, at the end of, and four weeks after treatment. Patients also completed a follow-up questionnaire on an average of five to six months after treatment. A significant improvement in the laser compared to the placebo group was found on visual analog scale ($p=0.02$) and grip strength ($p=0.03$) tests four weeks after treatment. In this study low level laser therapy was shown to have an effect over placebo; however, as a sole treatment for lateral epicondylitis it is of limited value. Further studies are needed to evaluate the reliability of our findings and to compare laser to other established treatment methods.

Key words: low level laser, tennis elbow, epicondylitis.

From the mid-eighties the interest in low level laser therapy has increased considerably (21). Most scientific work in this field has utilized continuous Helium-neon (HeNe) lasers with red light and/or pulsed Gallium-arsenide (GaAs) lasers with infrared light. The use of low level laser therapy is, however, hampered by the lack of systematic tests and investigations on the mechanisms and medical effects of low level laser light. Doubt has been raised about the efficacy of infrared lasers in pain (23), woundhealing (32), knee arthrosis (19) and nerve conduction (16, 26). Others have found effects in the treatment of woundhealing (12), pain (7) and rheumatoid arthritis (10, 15). In addition there exists a substantial amount of research that focus on the therapeutic use of HeNe lasers.

Few studies have focused on laser therapy for tendinitis (13, 14, 17, 18, 25, 30). The therapeutic effect of this treatment is reported to range from none (25, 30) to 80% cure rate (14). Two studies on lateral epicondylitis, commonly named tennis elbow, have given contradictory results. In one study, 30% of the patients were cured and another 68% improved at one month follow-up (17), whereas in a similiar study no significant improvement was noted (25).

The purpose of this study then was to document the efficacy of active versus placebo laser in the treatment of lateral epicondylitis.

PATIENTS AND METHODS

Thirty patients with lateral epicondylitis recruited from local physiotherapists and physicians participated in the study. There were 15 women and 15 men that ranged in age from 25–63 years with an average of 45.5 years. The duration of their symptoms ranged from 1–12 months with an average of 3.5 months.

Included in the study were patients with lateral epicondylitis confined to the tenoperiosteal junction of the extensor carpi radialis brevis. This was confirmed by increased pain in the area anterior to the lateral epicondyle upon both palpation and isometric wrist extension against manual resistance with the elbow kept fully extended. Excluded were those with arthrogenic, neurogenic, or muscular dysfunctions in the cervical area which upon provocation gave radiating pain into the arm. Also excluded were patients with RA, bilateral lateral epicondylitis, and those who had received other treatment regimes in the last 3 weeks before inclusion. The patients participating in the study were not allowed to receive any other treatment with respect to lateral epicondylitis between the inclusion and last control.

The study was approved by the regional medical ethics committee. All patients gave signed informed consent.

A block-design was used in this controlled, randomized double-blind study. The patients were divided in two blocks as follows: acute; symptoms less than six months, and chronic; symptoms more than six months. The patients were randomized to one of two treatment groups; A: Laser ($n=15$) and B: Placebo Laser ($n=15$). Balanced groups were attained utilizing patient blocks of six patients, where each block contained both treatment regimes in balanced proportions. The code was broken after the statistical analysis was concluded.

The group receiving active laser ($n=15$) consisted of nine

Table I. *Patients status upon inclusion and number of patients on sick-leave during the study*

NSAID = non-steroid anti-inflammatory drugs, SAID = steroid injection

	Active laser	Placebo laser
Sick-leave		
No	7	4
Yes	8	11
Previous treatment		
Physiotherapy	0	1
NSAID	6	7
SAID	5	4
Other	1	0
Etiology		
Unknown	6	5
Work	7	8
Leisure	2	2
Affected side		
Dominant	9	9
Not dominant	6	6

women and six men with a mean age of 47.1 years (range 34–63). The placebo group ($n=15$) consisted of six women and nine men with a mean age of 43.9 years (range 25–61). The average duration of symptoms was 4.1 (range 1–12) and 2.9 (range 1–10) months in the laser and placebo groups respectively. Eight patients in the laser and nine patients in the placebo group had received previous treatments. Nine patients (60%) in both groups were affected by tennis elbow in their dominant hand/arm. There was a tendency towards a larger frequency of sick leave in the placebo group. This was however not significant ($p2=0.23$). Otherwise, the groups were initially found to be clinically equal with regard to age, sex, duration of symptoms, etiology, previous treatment, and affected side (Table I).

Two identical infrared lasers of type Combi laser C501 (Schreuder Instrumenten, Holland) were used. This is a semiconductor GaAs laser with a 904 nm wavelength. A laser head with 12 diodes in an octangular fashion covering approximately 20 cm^2 was used. The repetition frequency was measured to 880 Hz and the pulse duration to 175 ns (HP 1652B; oscilloscope option, Oslo, Norway). The average effect from single diodes was 1.5 mW (Optical power meter ML93A, Anritsu, with a 10 mm Si-detector). The average peak effect was calculated from these measurements to 10 W. The irradiation area at a normal skin distance of 8 mm from the diode was 25 mm^2 detected with an IR-sensitive fluorescent paper. When applied for 10 min, this gave a dose on the skin surface of 3.5 J/cm^2. The lasers were calibrated before, during, and after the study.

The lasers were numbered 1 and 2, but otherwise they looked identical, when used in treatment. One of the lasers were effective, and in the other the cables to the diodes inside the laser were disconnected so that no light was emitted. Both the physiotherapist and the patient were blinded as to which was the effective laser and which was the placebo laser.

All patients were given 8 treatments of 10 min at a frequency of three times per week. Each patient was evaluated subjectively and objectively at inclusion, end of treatment, and at the last control four weeks after the treatment period. All individual evaluations were performed by the same physiotherapist. The following effect-variables were utilized:

Vigorimeter (Martin): The highest value of three attempts at maximum grip strength was recorded both on the affected and the non-affected side. The elbow was kept between 40–60 degrees of flexion.

Weight test (free weights): The ability to lift 0 (hand only), 1, 2, and 3 kg in wrist extension without pain with the elbow fully extended and the forearm pronated was evaluated on the affected side only. The forearm was supported on a table with the shoulder in 60 degrees of flexion.

Goniometric measurements of wrist flexion: The point of aggrevation of pain as the wrist was flexed was recorded in degrees on both sides. The elbow was kept fully extended and the forearm pronated.

Visual analog scale (VAS): The patients were asked to judge the intensity of their pain on a 10 cm straight line (0=no pain and 10=severe pain) on the basis of the last 24 hours prior to each evaluation.

Patient assessment: At the end of the treatment period and at the last control, the patients were asked to assess their status from the following alternatives: worse, no change, somewhat better, much better, no pain.

There was one drop-out in our study who in the period between the end of the treatment and the last control mistakenly started on antiflogistica. Since no other relevant treatment was to be taken before the last control, the patient had to be dropped from the study (drop-out type A). A new patient was included in order to maintain balanced groups.

Statistical analysis

Except for frequencies, all results are expressed as mean values with 95% confidence intervals. The Student Procedure was used for construction of the confidence intervals. Frequencies are given in observed numbers.

Comparisons of the groups with regard to the initial situation were carried out two-tailed and marked by *p2* in the results. Based on *a priori* knowledge, comparison of effects between active and placebo treatment was carried out one-tailed. Differences were considered significant if the *p*-values were less or equal to a level of 5%.

Categorizing data analysis was used for comparisons of the groups with regard to frequencies. For assumed continuously distributed variables analysis of variance was used for comparisons of the groups. Student's test for pared samples was used for testing changes within groups.

RESULTS

Subjective data

In the laser group, there was a significant decrease in pain as measured by VAS from inclusion to the end of treatment ($p=0.047$) and from inclusion to the last control ($p<0.01$), (Fig. 1). No significant decrease in pain was seen from the end of treatment to the last control ($p=0.10$) in the laser group. In the placebo

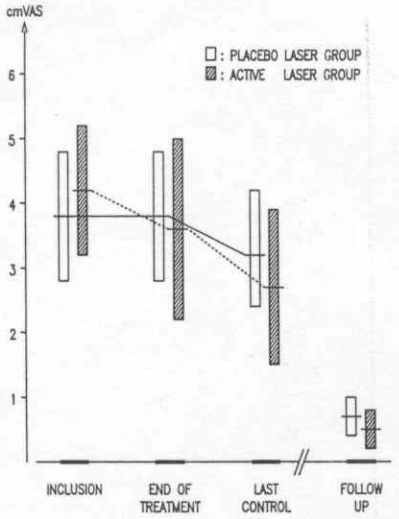

Fig. 1. Comparisons of active and placebo laser groups with respect to VAS scores. Each column gives the mean value with a 95% confidence interval. Data are given for start and end of treatment ("inclusion" and "end of treatment") and four weeks after treatment ("last control"). It should be emphasized that the study ended at the last control (see Fig.). Some patients needed additional treatments in the period between the last control and the follow-up session, and received various other treatment regimes until painfree or almost painfree (see text).

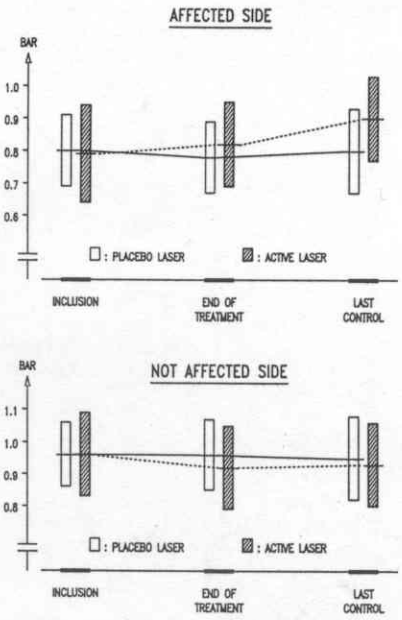

Fig. 2. Comparison of grip strength (bar) in the active and placebo laser group both on the affected and non-affected side. Each column gives the mean value with a 95% confidence interval.

group, no significant effect was found from inclusion to the last control on VAS (Fig. 1). A similar tendency was prevalent in the patients' judgement of progress; 7 patients (47%) in the laser versus 3 patients (20%) in the placebo group classified themselves in the "much better/no pain" group at the last control (Table II). In comparing the changes on VAS scores in the two groups; the laser group showed a significant decrease in pain over the placebo group on VAS from inclusion to the end of treatment ($p=0.04$), and from inclusion to the last control ($p=0.02$). There was however no significant difference in the *VAS score values* between the laser and the placebo laser group at inclusion ($p=0.34$), at the end of treatment ($p=0.40$) or at the last control ($p=0.11$).

Table II. *Patients verbal judgement of progress*

	End of treatment		Four-week follow-up	
	Laser	Placebo	Laser	Placebo
Worse	2	2	2	2
No change	3	5	1	5
Slightly better	7	8	5	5
Much better/no pain	3	0	7	3

Objective data

There was a significant improvement in grip strength on the affected side from inclusion to the last control ($p=0.02$) in the laser group, but no significant improvement from inclusion to the end of treatment ($p=0.34$) or from the end of treatment to the last control ($p=0.08$), (Fig. 2). The weight test showed a significant improvement in the laser group from in-

Table III. *The table shows the mean values on weight test on affected side and painfree flexion in the wrist, both on the affected and the non-affected side*

Confidence intervals of 95% are given in parenthesis. The numbers 1, 2 and 3 indicate evaluation at inclusion, end of treatment, and last control, respectively

Variables	Active laser	Placebo laser
Weight-test (kg)		
1	1.1 (0.7–1.5)	1.0 (0.5–1.5)
2	1.2 (0.7–1.7)	0.9 (0.5–1.3)
3	1.7 (1.2–2.2)	1.2 (0.6–1.8)
Goniometric flexion (degree)		
Affected side		
1	78 (70–86)	78 (71–85)
2	80 (72–88)	83 (75–91)
3	81 (74–88)	80 (72–88)
Not affected side		
1	87 (83–91)	86 (80–92)
2	88 (84–92)	86 (78–94)
3	87 (82–92)	87 (79–95)

clusion to the last control ($p=0.02$), but not from inclusion to the end of treatment ($p=0.42$) nor from the end of treatment to the last control ($p=0.07$), (Table III). Comparison between the groups showed significant improvement only in grip strength from inclusion to the last control ($p=0.03$) in the laser over the placebo group. There was no significant difference in the *grip strength score values* between the laser and the placebo laser groups at inclusion ($p=0.41$), at the end of treatment ($p=0.30$) or the last control ($p=0.26$). No significant improvement was found in wrist flexion in the laser group (Table III). No significant improvements was found in the placebo group for any of the effect variables tested.

Questionnaire

A follow-up questionnaire was mailed to all but two patients in the placebo group. These two were omitted because they had just completed the study. There was a mean duration since the last treatment of 5.5 months (range 2–9 months) in the laser group and 5.6 months (range 2–9 months) in the placebo group. Seven patients in the laser group (7/15; 47%) and nine patients in the placebo group (9/13; 69%) needed further treatment after the last control. The patients received one or more of the following treatment regimes; deep friction massage, ultrasound, *active* laser, or acupuncture. The patients in the laser group needed on the average 5.4 treatments (range 0–18) in order to return to their daily activities with minor or no pain, while the respective numbers in the placebo group were 8.2 treatments (range 0–22). As to the patients' own judgement, 47% (7/15) in the laser versus 38% (5/13) in the placebo group regarded themselves as completely/almost completely painfree. Both groups showed a substantial improvement on VAS (Fig. 1). In general terms, there is a tendency towards a better outcome in the laser compared to the placebo group also at five to six months follow-up (Table IV).

Table IV. *Questionnaire follow-up at 5–6 months post-treatment*

Variables	Scores	Active laser $n=15$	Placebo laser $n=13$
Pain	No pain	7	5
	Pain sometimes	7	8
	Pain often	1	0
Treatments after participating in the study	No	8	4
	Yes	7	9
Working situation	In work	13	9
	Not in work	1	2
	Other	1	2
Pain in work situation	Minor/no pain	12	5
	Pain at times	2	6
	Pain inhibiting work	1	2

DISCUSSION

Our groups turned out well-balanced in all respects. Some patients felt that the four week follow-up period was long. However, to our knowledge no comparable studies have emphasized a follow-up period of this length and manner and, thus; we felt this period to be justified from a methodical point of view. The delayed effects of the therapy involved in this study, clearly shows the importance of a follow-up period of some length in studies of this kind.

Although some individual variances exist, it seems

that grip strength is a valid test in diagnosing and evaluating the progress of tennis elbow (31). On the other hand, the goniometric measurements of pain-free wrist flexion did not reveal these differences and we feel that this test is redundant in studies comparable to ours. We felt the free weight test to be a good diagnostic and prognostic test. Smaller weight intervals may however reveal differences more precisely. The patients' progress as reflected in the VAS and grip strength results showed a close conformity, justifying the use of both tests in future studies of this kind. The validity of VAS is thoroughly documented previously (1, 24).

There is little evidence in the literature giving clues to the optimal dosage of laser energy with regard to intensity, frequency, wavelength, peak pulse etc. on the one hand and to the various pathological conditions on the other. We chose to use a dosage close to one already used in a study with favourable effects of laser therapy on tendinitis (17). Unfortunately, few publications state measured readouts and appropriate nomenclature regarding laser energy. The importance of accurate information in this respect are emphasized in previous publications (2, 22).

Over 40 suggested treatment regimes for tennis elbow have been described (8). In a study of ultrasound treatment, 63% of the patients were shown to improve (4). In a 3–12 month follow-up study of acupuncture versus steroid injection, 61% versus 31% of the patients in each group respectively reported to be in the much better–no pain category (6). In a study comparing acupuncture to laser therapy for tennis elbow, 93% in the acupuncture versus 45% in the laser group was almost or completely painfree at the three-month follow-up (18). Non-steroidal anti-inflammatory drugs are often used but evidence for their efficacy is tenuous (8). One study reported a 50% cure rate after one injection of betamethasone compared with 55% cure rate using 250 mg of naproxen (29). In a study with a six-month follow-up, 36% of the patients receiving steroid injection versus 18% receiving no injections got complete or partial relief of their symptoms (3), while yet another study showed a 92% cure/much improved rate with steroid injection (11). However, relapse rates between 18% and 50% at six-month follow-up after steroid injection have been reported (5, 9, 27), and over 40% have been shown to have minor discomfort affecting some activities, in some persisting for five years (5). In one study where patients had between two and five injections of a depot preparation of cortison, 17% suffered either depigmentation and/or necrosis of subcutaneous fat (28). Surgery is used in resistant cases. Success rates are reported in the 73%–93% range (20). The long term follow-up in several of these studies might however cover the fact that a great number of these patients might have recovered without surgery due to the self-limiting nature of this pathology (20). The pathology of tennis elbow remains an enigma, making the choice of surgical technique difficult (20).

We found that active laser does have a significant effect on tennis elbow with regards to decreased pain measured by VAS, increased grip strength measured by vigorimeter and increased wrist extension strength measured by the ability to lift free weights. The strength in the results could have been further enhanced if we had increased the number of patients in our study. The small patient number with 15 in each group gives us a type 2 error of 15% to detect differences equal to one time the standard deviations. Subjectively, 80% of the patients in the laser versus 53% in the placebo group stated to be improved over the seven week course of this study. Of these, 47% in the laser compared to 20% in the placebo group stated to be much better or completely relieved of their symptoms. The subjective improvement reported in the placebo group by the patients own verbal judgement was high, but this was, however, not reflected in the objective test variables nor on the VAS, indicating the importance of caution in the selection of evaluation parameters in studies of this kind.

Even though we have shown that laser does have an effect upon lateral epicondylitis, we feel that this treatment used alone is of limited value. It would be interesting to know how this effect compares to other frequently used treatment methods. An investigation to compare laser to traditional physiotherapeutic treatment methods is now in progress.

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Address for offprints:

Ottar Vasseljen Jr
Institutt for Org. og Arb.livsfag
Universitetet i Trondheim/NTH
7034 Trondheim
Norway