Low Level Laser Therapy for Myofascial Pain in the Neck and Shoulder Girdle. A Double-blind, Cross-over Study

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In a controlled, cross-over study the effect of low level laser therapy (LLLT) was evaluated. During a five weeks period forty-seven female laboratory technicians received six laser and six placebo treatments to tender points in the neck and shoulder girdle. Subjects rated the placebo treatment significantly more beneficial than LLLT ($p = .04$). There was no reduction in consumption of analgesics associated with either laser or placebo treatment. The results indicate no beneficial effect of LLLT for myofascial pain.

Key words: Low level laser therapy, myofascial pain, shoulder girdle, Ga-Al-As.

Since Low Level Laser Therapy (LLLT) was introduced in the late sixties for rheumatic diseases, its place in physiotherapy has been controversial. Several National Health Committees have refused to refund LLLT by the public health security system. Double-blind studies using LLLT have failed to show beneficial effect on myofascial pain (1–5). Some studies reporting beneficial effect of LLLT for myofascial pain are inadequately blinded (6–8).

We have previously reported on a controlled study of LLLT (Ga-Al-AS, wavelength 830 nm) applied to myofascial pain in the shoulder-girdle (9). In that study, the effects of LLLT and placebo were assessed by indices of pain at rest, pain on function and changes in selfmedication for pain. The measures showed no significant differences between LLLT and placebo, while the subjects expressed a preference for LLLT. We concluded that the study showed LLLT to be of no value in the treatment of myofascial pain in the shoulder-girdle. However, due to the preference expressed for LLLT, the present study of LLLT was planned.

Subjects and Methods

A letter was sent to all female laboratory technicians employed at three hospitals in the Copenhagen area (475 letters) inviting them to participate in the study if they had neck or shoulder troubles. After an examination by a physician, the technicians were included in the study if they fulfilled the following criteria: 1) Age 18–65 years; 2) pain from the neck and shoulder-girdle lasting at least one year, affecting the quality of work or daily living; 3) between one and ten tender points in the shoulder-girdle, tender points that on palpation induced reproduction of the reported symptoms.

Subjects who abused alcohol, had a general disease, classic migraine or who were pregnant, were excluded from the study.

Subjects were randomly selected to either active or placebo laser as they entered the study. Initial treatment consisted of six sessions over a two-week period. On completion of this phase of the study, treatment was suspended for one week. The subjects then crossed over to receive the opposite treatment. Before each treatment session the physiotherapist palpated the tender points (up to ten) and each point was given one minute of treatment. The probe was in contact with the skin at a right angle.

The laser apparatus used in the study was an Endolaser 465 class 3B manufactured by Enraf Nonius, Hvidovre, DK. It was fitted with a 830 nm ± 0.5 nm, 30 mWatt, Ga-Al-As diode. The beam divergence was 4 degrees and the area of probe-head 2,5 mm^2. The Endolaser 465 was fitted with a switch to change between active and placebo laser, marked F and N in the study. The treatment was carried out in a private physiotherapy practice.

During an active laser treatment period each subject received 0,9 J per treated point and a maximum of 9 J per treatment.

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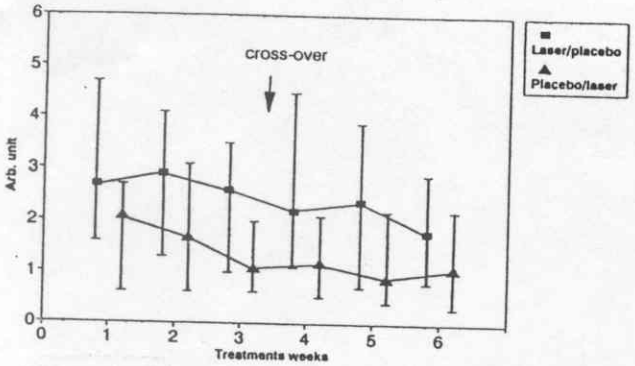

Fig. 1. The results of $VAS^{function}$ during the six weeks of the study with medians and quartile percentiles. In the weeks 2, 3, 5 and 6 the subjects received treatment.

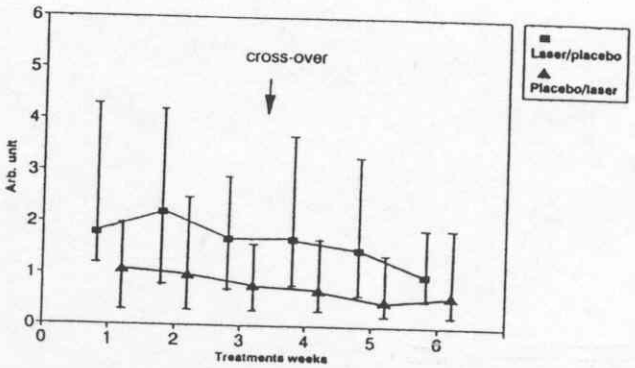

Fig. 2. The results of VAS^{pain} during the six weeks of the study with medians and quartile percentiles. In the weeks 2, 3, 5 and 6 the subjects received treatment.

In addition, the Endolaser could be switched between continuous and pulse mode. The first 25 subjects recruited received continuous and the remainder pulse mode treatment. To protect the blind design of the study the light measuring diode was disconnected. Instead, the laser was tested every second week by the manufacturer. There was no way of telling whether the laser was set for laser light or placebo mode of operation. The active and placebo settings were identical in terms of sound, heat and vibration emitted. In the placebo setting, the emitted red light was of an intensity and wavelength indistinguishable from the laser light. Subject, therapist and data analysts were unaware of the code for active or placebo laser until the data analysis was complete.

Visual analogue scales (VAS) were constructed of 10 cm lines marked at one end by "no pain" and at the other "unbearable pain " with no intermediate indications. The subjects marked on the scales each day over a period of six weeks, starting one week before the beginning of the treatments. The subjects also indicated their daily consumption of analgesics. At the end of each week, during the course of the treatment, the subjects were asked if they had noticed any benefit. At the end of the study all subjects were asked about their symptom experience. Before data analysis the five physiotherapists completed a short questionnaire to determine, which switch (F or N) they thought was the active one.

Non-parametric and parametric statistical tests were selected for the data analysis. A significance level of $\alpha = .05$ was chosen.

The study was approved by the local ethical committee.

Results

Fifty-two subjects volunteered to participate in the study. They all met the inclusion criteria. Three withdrew before the first period of the study due to lack of time or illness in the family. A further two withdrew during the first week of the study due to unacceptable side effects (nausea and aggravation of symptoms). These two subjects were receiving treatment with the placebo laser. Only one of these two had filled in the baseline questionnaire.

The data analyses presented are therefore based on forty-seven subjects. The mean age of the sample was 41, with a range from 23 to 65 years. Symptoms had been present for a mean of five years (range, 1–20). The subjects were employed for 20–37 hours a week, with a mean of 35 hours.

The two groups of laser-treated persons were combined for statistical analysis, because no statistically significant differences (Mann-Whitney) were found between the effect of continuous and pulse laser treatment.

Twenty subjects (43%) reported beneficial effect of the placebo treatment, eight subjects (17%) of the laser, thirteen (27%) reported no effect of any treatment and six (13%) reported effect during both. A Sign test showed a significant difference in favour of placebo ($p = .04$, confidence interval 3.5–47.6%).

At the start of the study, the laser/placebo group (n=25) was significantly different from the pla-

Table I. Analgesic tablet consumption during the six weeks of the study. In the weeks 2, 3, 5 and 6 the subjects received treatment.

Week	Laser/Placebo sequence Median 25–75 percentiles		Placebo/Laser sequence Median 25–75 percentiles	
	no = 25		no = 22	
	Analgesics			
1	0.3	0–3.9	0.5	0–5.9
2	0.3	0–4.2	1.0	0–3.7
3	0.3	0–1.9	0.4	0–3.6
4	0.3	0–2.5	0.3	0–2.5
5	0.3	0–3.0	0.1	0–2.6
6	0.2	0–2.5	0.3	0–2.5

cebo/laser group (n=22) in respect of $VAS^{function}$ ($p = .021$), VAS^{rest} ($p = .03$) and analgesic tablet consumption ($p = .013$), (Mann-Whitney).

In figures 1 and 2 the median values of $VAS^{function}$ and VAS^{rest} with quartile percentiles are given. Data were tested (Friedmann) for carry-over and period effect which were found.

The same analyses were done for consumption of analgesics, values given in table I, but did not reveal any carry-over or period effect. A reason for this may be that only a few of the subjects consumed any analgesics.

The imbalance in baseline values were taken into account in an additional analysis by including these values in a linear regression model with dummy variables for laser and placebo. No difference in the final values after three weeks was found between laser and placebo neither for $VAS^{function}$ ($p = .49$) nor for VAS^{rest} ($p = .75$)

No difference was found between the laser group and the placebo group in mean analgesic consumption during the study (Wilcoxson).

At the end of the study five subjects (12%) reported no symptoms, nineteen (40%) fewer, twenty-two (46%) reported no change in symptoms, and one (2%) reported more symptoms.

All five physiotherapists judged the N position (placebo laser) to be the active one.

Discussion

This study confirms our previous findings of the lack of effect with LLLT for myofascial pain in the neck and shoulder-girdle (9). Our results also confirm earlier controlled studies where different areas with myofascial pain were treated (1–5). The type of laser (He-Ne, GaAs, Ga-Al-As), wavelength, mode (continuous/pulse), and doses used in the above mentioned studies vary. Lundeberg (4) applied He-Ne and Ga-As to two different groups of patients and found no difference between them.

It is commonly claimed by manufacturers of low level laser equipment that a high dose is essential to achieve pain reduction. This encouraged us to use a higher dose than in previous studies. However, these higher doses had no effect on pain.

A statistically significant reduction in myofascial pain was found in this study although it was associated with placebo rather than with active treatment. This was only true for one of the variables, the general effect, but was not reflected in other variables. This leaves an open question on the validity of measuring pain with visual analogue scales or a global assessment by participants.

The effect of intervention is surprisingly great in this study considering the duration of symptoms (mean = 5 years), indicating the subjects positive attitude to LLLT and a heavy regression towards the mean.

The greater improvement with the placebo treatment is properly explained by the physiotherapists' beliefs that the inactive position of the switch on the laser was actually the active one. It is likely that the reported improvements in symptoms resulted from the major influence that the therapists have on patients. Such a process may well also explain positive findings in earlier studies, where blinding was inadequate (6–8).

The results of this controlled study, together with those from other similar studies indicate that it is not possible to achieve myofascial pain reduction with LLLT under strictly blinded conditions.

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