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# Low Energy Laser Therapy in Rheumatoid Arthritis

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Low energy laser (LEL) is a widely used treatment for a variety of musculoskeletal disorders although convincing documentation of the effect is missing. We have examined the LEL effect on Rheumatoid Arthritis (RA) in a double blind placebo controlled study. Twenty-two patients completed the study (10 receiving LEL treatment) according to the protocol. A significant effect on pain score was found due to LEL treatment, but when data were corrected for disease variation the effect disappeared. No effect of LEL could be demonstrated on the other assessed variables: grip strength, morning stiffness, flexibility, erythrocyte sedimentation rate (ESR), C-reactive protein (CRP). In conclusion, we did not find that LEL had any clinically relevant effects on RA.

Key words: rheumatoid arthritis, laser treatment, extra-articular treatment, metacarpophalangeal joints

Low energy laser (LEL) is a widely used treatment for a variety of musculoskeletal disorders. *In vitro* studies on LEL effect have demonstrated a change in the metabolism of cell cultures indicating a possible immunomodulating effect of LEL (1). However, *in vivo* the laser specific properties change quickly after penetrating the skin (2), which makes a specific laser effect on cells doubtful. Also in clinic studies convincing documentation of the effect is missing (3, 4), making the use of LEL controversial. In a recently published meta-analysis of the LEL effect on musculoskeletal pain, Gam et al. (4) concluded that LEL was without effect. We have found 4 controlled studies on LEL treatment of Rheumatoid Arthritis (RA) (5–8). In these studies different laser types, different wave lengths and effects have been used, which makes comparison difficult.

Goldman et al. (5) found in a single blinded placebo controlled study an effect of laser therapy on RA finger joints compared to the contralateral untreated joints. All 30 patients noted burning sensations during laser treatment, which makes the single-blinding very doubtful, especially as they were their own controls. It must also be emphasized that a laser treatment with a much higher effect than recommended for LEL was used.

In the study by Walker et al. (6) the blinding was also doubtful, as the active laser emitted light and the placebo laser did not. The patients were evaluated on a weekly basis and not until week 9 and 10 was a significant change in pain ratings found within the laser treated group. No values of differences between the laser treated and the placebo treated groups were given. Bliddal et al. (7) used the opposite hand as a control. No significant differences were found within or between groups in a joint ability score. Pain was evaluated on a visual analogue scale, but transformed into a binominal scale. Although 11 out of 17 patients did not feel any difference between laser and placebo treatment the Sign test was used on the 6 patients that felt a difference, and only then a significant difference could be found after 3 weeks of treatment. Palmgren et al. (8) found in a double blinded study a significant effect of laser on grip strength, swelling of treated joints, tip-palm distance, morning stiffness and pain level, whereas the placebo treated group only experienced a significant decline in pain level. No comparison between groups was however calculated although this was planned according to Material and Methods.

To evaluate whether LEL could be recommended to RA patients in a rheumatologic department we conducted a double blind placebo controlled clinical study.

## Material and Methods

Twenty-four consecutive patients with RA, fulfilling the American Rheumatism Association (ARA) criteria 1987, were included in the study after informed consent. Eligibility was confined to patients aged 18–85 years in Steinbrocker functional class I or II (9) with active RA (defined as more than three inflamed joints, disregarding activity level) and symmetrical involvement of the metacarpophalangeal (MCP) joints. Patients with bony erosions or osteoarthritis on X-ray of the MCP- or interphalangeal (IP) joints of the fingers were excluded. Pregnant patients and patients with other inflammatory rheumatic diseases were also excluded. Changes in steroid, NSAID and analgetics were not accepted within the last month before entry and during the study. Changes in disease modifying anti-rheumatic drugs (DMARD) were not accepted

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Table I. Median values, 25% percentiles in brackets, of background and outcome variables of the 22 patients who completed the study according to the protocol. The assessed variables after treatment in the treated hand were corrected for disease variation by subtracting the change in the similar variables in the other hand giving a "corrected assessment". *: significant change within a group (Wilcoxon-Pratt, p = 0.015). No differences between groups were found before or after treatment (Mann-Whitney).

| Assessment | | | LEL-treatment (n = 10) | Placebo-treatment (n = 12) |
|---|---|---|---|---|
| Pain score (0–12) | Before | treatment | 7 (5.8–9.0) | 6.5 (5.3–8.8) |
| | After treatment | uncorrected | 4.5 (3.8–7.3)* | 5.5 (2.3–9.5) |
| | | corrected | 7 (2.8–10.3) | 5.5 (3.0–8.8) |
| Grip strength (kg) | Before | treatment | 6.2 (3.5–11.5) | 5.3 (4.3–9.8) |
| | After treatment | uncorrected | 7.0 (4.3–11.0) | 6.5 (3.0–10.5) |
| | | corrected | 6.5 (1.5–11.8) | 5.5 (3.3–10.3) |
| Flexibility tip-palm distance (cm) | Before | treatment | 0.25 (0.0–1.0) | 1.0 (0.5–2.9) |
| | After treatment | uncorrected | 0.0 (0.0–0.9) | 1.25 (0.0–4.5) |
| | | corrected | 0.5 (0.0–2.25) | 0.75 (0.1–2.9) |
| CRP (nmol) | Before | treatment | 154 (29–431) | 263 (113–534) |
| | After | treatment | 96 (30–630) | 216 (122–470) |
| ESR (mm/h) | Before | treatment | 32 (10–59) | 36 (19–77) |
| | After | treatment | 12 (5–45) | 32 (14–95) |

Abbreviations: LEL = Low energy laser, ESR = Erythrocyte sedimentation rate, CRP = C-reactive protein.

within the last 3 months before entry and during the study. No other therapies were allowed during the study.

All patients included were randomised by pulling envelopes into two groups, receiving either laser therapy or dummy laser treatment. The real lasers and the dummy lasers were similar, and for the patients and therapists undistinguishable, both giving red visible light.

Randomisation was performed by an independent employee, who did not participate in the treatments or assesments, and who handed over the apparatus to the therapists before each treatment.

We used a Gallium-Arsenid-Aluminium (GaAsAl) laser with a wave length of 830 nm, continous laser beam and a spotsize of 0.07 $cm^2$ (P-laser International, Egedalsvej 9, DK-3670 Veksø). An effect of 30 mWatt by the delivered apparatus was expected and planned for the study. However after 9 patients had been included in a prestudy, a control of the active laser was carried out (Light and Optics, DTH, Copenhagen). The test showed that the effect of the active laser was only 10% of that expected. Another apparatus with 21 mWatt effect (70% of the expected effect) was delivered and accepted for the study. This was tested before and after the study and showed a steady effect. In order to reach the planned energy the treatment time was increased. In all 23.2 J were applied per treatment with 2.9 J on four points (two anterolateral and two posterolateral) around each of two MCP joints. The two most painful MCP joints on the most affected hand were chosen for treatment. Treatments were offered three times a week for a month. Absence for more than three times led to exclusion, thus all patients fulfilling the study had 9–12 treatments.

## Evaluation

The same two blinded assessors evaluated the patients at the study entry and after 1 month of therapy. The following variables were assessed for the two treated MCP joints and their contralateral joints: pain at rest in each individual MCP joint was registered on an ordinal box scale ranging from no pain (0) to highest possible pain (3). Joint tenderness was registered on a similar ordinal box scale (0–3) by pinching each MCP joint with two fingers. A pain score was calculated for two joints on each hand by adding pain at rest and joint tenderness (total score range 0–12). Flexibility was measured by the sum of tip palm distances in cm. Grip strength for both hands was measured in kilograms (kg) by a handheld digital dynamometer (MY-Gripper, Smith & Nephew). Duration of morning stiffness was indicated on an ordinal box scale (0–2): "0": <½ h morning stiffness; "1": ½–1 h; "2": >1 h. C-reactive protein (CRP) and ehrocyte sedimentation rate (ESR) were measured before and after treatment. All adverse effects were registered.

As disease activity in RA fluctuates, the assessed variables after treatment in the treated hand were cor-

rected by subtracting the change in the similar variables in the other hand giving a so-called corrected assessment. At evaluation of the results the laser/placebo code was broken.

### Statistics

Differences in variables within a treatment group were analysed by non-parametric Wilcoxon-Pratt test for paired data, and differences between groups by non parametric Mann-Whitney test for unpaired data. A significance level of 0.05 (two tailed) was chosen a priori.

## Results

Twenty-two patients completed the study according to the protocol. Ten patients (9 women, median age 59 years, 25% percentiles 36–76 years) received LEL treatment, and 12 patients (10 women, median age 62 years, 25% percentiles 56–73 years) received placebo treatment. In table I the entry assessments are presented. Only the treated joints are included in the data presentation. No significant differences were found between the two groups at entry (Mann-Whitney).

The effect of LEL- and placebo treatment on the outcome variables is also shown in table I. A significant effect on pain score was found in the LEL treated group, but this effect disappeared after correction for disease variation. For all other variables no significant effect was found within groups and for none of the variables between groups.

Among the patients receiving LEL treatment 60% (6/10) indicated the same morning stiffness after treatment as at entry; 30% (3/10) indicated improvement, and 10% (1/10) indicated increased stiffness. Among the patients receiving placebo treatment 83% (10/12) indicated unchanged morning stiffness, 8% (1/12) improved and 8% (1/12) worsened stiffness.

Adverse effects were expressed by four patients. In two patients receiving LEL treatment, disease activity increased necessitating steroid treatment whereupon they were withdrawn. Two other patients, one from each treatment group, complained of burning sensations on the treated joints, but completed the trial.

## Discussion

In our study we actually found an effect of LEL therapy on the pain score. But when attempting to correct data for disease variation, this effect disappeared. If, in fact, LEL has an immunomodulating effect as suggested by Goldman et al. (5) and Palmgren et al. (8), this effect will be overshadowed by the correction. On the other hand, a decrease in disease activity judged by improvement in the not treated hand (Goldman et al. (5)) or by ESR and leucocytes (Palmgren (8)) is not necessarily due to an immunomodulating effect, but could as well be explained by spontaneous RA fluctuation. Our attempt to correct for the disease activity was based on the assumption that fluctuations in joint activity are symmetrical, which might be questioned.

The systemic outcome variables (ESR, CRP) were not affected by LEL treatment in our study, in contrast to the study of Palmgren et al. (8). On the other assessed variables no effect of LEL treatment could be demonstrated with or without correction, further indicating that LEL treatment is without effect on RA.

In conclusion: No effect of LEL treatment on RA was found in our study. To demonstrate a potential minor effect of LEL on RA joints, studies based on larger patient groups would be required. As treatment with LEL is time consuming and expensive, we regard a minor effect as clinically irrelevant.

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