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LOW LEVEL LASER THERAPY IS INEFFECTIVE IN THE MANAGEMENT OF RHEUMATOID ARTHRITIC FINGER JOINTS

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SUMMARY

Low level laser therapy (LLLT) is a relatively new and increasingly popular form of electrotherapy. It is used by physiotherapists in the treatment of a wide variety of conditions including RA despite the lack of scientific evidence to support its efficacy.

A randomized, double-blind and placebo-controlled study was conducted to evaluate the efficacy of LLLT. The patient sample consisted of chronic RA patients with active finger joint synovitis.

Forty RA patients with involvement of some or all of MCP or PIP joints were recruited. Following random allocation they received either active or placebo laser three times a week for 4 weeks. Measurements were taken prior to entry, after the treatment, 1 month and 3 months at follow-up. The groups were well matched in terms of age, sex, disease duration and severity. Few significant differences were noted in grip strength, duration of morning stiffness, joint tenderness, temperature of inflamed joints, range of movement or pain either within or between groups. Using these irradiation parameters the efficacy of LLLT is ineffective.

KEY WORDS: Low level laser therapy; Rheumatoid arthritis; Physiotherapy.

PHYSIOTHERAPY in RA is generally accepted as a useful adjunct in the overall management and a considerable number of treatments are advocated [1]. One of these, low level laser therapy (LLLT), a term introduced by Ohshiro and Calderhead [2], has recently been introduced into physiotherapy departments.

Reports in the literature suggest that LLLT may be effective for a wide variety of disorders including wound healing [3], soft tissue lesions [4, 5], pain relief [6, 7] and rheumatic complaints including pain and inflammation. The findings from studies conducted on patients with RA are contradictory and the controversy is heightened when differences in machine and treatment specifications and injudicious study design are considered [8–14]. Furthermore it is often difficult to determine the clinical value despite some impressive statistical significance levels.

Despite the increasing popularity and use of LLLT the mechanism of action remains unknown. The low power outputs used in these lasers do not produce appreciable temperature changes in the treated tissue. Thus any benefits must be attributed to a non-thermal process resulting from interaction with, or absorption in specific tissues [15]. It is this photochemical effect, dependent on wavelength and frequency, which is considered to cause biostimulatory modulation. Palmgren *et al.* [9] speculates that stimulation of macrophages, together with laser induced excitation of inflamed synovial cells may result in removal of immune complexes. Herbert *et al.* [16] note that swollen joints are subject to ischaemia resulting in a fall in adenosine triphosphate (ATP) in the tissues and hence a reduced capacity for biosynthesis. Using laser light at 820 nm he demonstrated that ATP levels, *in vitro*, were increased and speculated that 're-energization' of the cells may be responsible for the efficacy of lasers. Considerable work remains to be undertaken, both *in vitro* and *in vivo*, to substantiate these hypotheses and provide a sound physiological basis for the use of LLLT.

The aim of this randomized, double-blind and placebo-controlled study was to assess the efficacy of LLLT in terms of disease activity and functional status in patients with RA and active involvement of the finger joints.

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PATIENTS AND METHODS

Patients

Forty patients with stage II or III, according to the Steinbocker *et al.* [17], classification of definite RA and who presented with active synovitis of some or all of the MCP or PIP joints were recruited. Patients who had undergone recent drug changes (within 30 days of trial entry for NSAIDs or 3 months for DMARDs) were excluded. Also those patients whose joints were incapable of response for mechanical reasons, for example due to bony ankylosis (stage IV), joint replacement or tendon rupture were excluded. Patients were recruited from outpatient clinics at the Royal National Hospital for Rheumatic Diseases, Bath following their informed consent. After an initial assessment suitable patients were randomly allocated to treatment with either the active or placebo laser. The hand which the patient considered most affected was treated, and in most cases this was the dominant (active group: 55%; placebo: 75%).

Equipment and procedure

The low power galium–aluminium–arsenide laser Biotherapy 3, manufactured by Omega Universal Technologies, was used. Both the single and cluster probes were used in a treatment lasting 18 min. Table I

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TABLE I
Treatment parameters

Single probe:
1. Spot size, 0.1 cm^2
2. Pulsing frequency, 5 kHz
3. Rated output, 50 mW
4. Actual output, 40 mW (80% duty cycle)
5. Irradiance, 400 mW/Cm^2
6. Wavelength, 820 nm
7. Beam divergence, 6°
8. Joints treated: the radial, ulnar, dorsal and ventral aspects of the first to fifth MCP and PIP joint lines of the most affected hand
9. Treatment method, the laser was held perpendicular to each of the joint positions in contact
10. Exposure time for each treated joint, 90 s
11. Energy dosage for each treated joint, 3.6 J
12. Radiant exposure for each joint treated 36 J/cm^2

Cluster probe:
1. Consists of 31 diodes with the following wavelengths and power outputs:
   8 × 880 nm (25 mW)
   10 × 870 nm (15 mW)
   14 × 950 nm (25 mW)
   1 × 820 nm (15 mW)
2. Total power output, 60 mW
3. Spot size of each diode, 0.1 cm^2
4. Total treatment time, 180 s over the dorsal and ventral aspects of the hand
5. Minimal radiant exposure, 27 J/cm^2
6. Maximal radiant exposure, 4.5 J/cm^2

details the treatment parameters. Because the cluster diode consists of 31 diodes and emits a variety of power outputs the minimal and maximal radiant exposures were calculated. The rationale for including the cluster head rests on wavelength specificity and Baxter's survey showed current clinical practice favoured this method [18].

The laser and dummy laser probes were coded for the duration of the trial and neither the treating physiotherapist, patient or investigator knew which machine was used. Patients were treated three times a week for 4 weeks by a specially trained physiotherapist.

The treatment schedule was devised to allow comparisons with other studies [9]. Furthermore at wavelengths around 820 nm penetration depths of 3–4 cm have been recorded [19] and treating the small joints of the hand would appear to offer the most promising outcome [10].

Measurements

Measures of disease activity and functional status were completed on four occasions by the investigator: prior to the start of the trial, immediately after the 12-treatment sessions and 1 month and 3 months after the treatment had ended. Patients completed the assessment procedures on each occasion at the same time of day to avoid any effects from circadian rhythms [20].

The duration of morning stiffness and the Ritchie index [21] were used as measures of disease activity. Additionally blood samples were analysed for haemoglobin, platelet count and CRP. Infra-red thermography of both hands, a quantitative and objective measure of inflammation, was used to record temperature changes over the small hand joints [22, 23]. This technique is performed in a temperature controlled room after a period of stabilization to a standard protocol. The thermographic index was calculated from the thermal scan by image processing. Normal values for this index over the hand are less than 3. Thermographic and biochemical data was collected on three occasions only: before and after the treatment period and at the 3-month follow-up. Swelling of the PIP joints was measured using an arthrocircometer (Ciba-Geigy) [24] and the mean for the affected hand used in the analysis. Swelling of the MCP joints was measured by encircling these joints with a tape measure, with the hand in the close packed position.

Hand strength, range of movement and pain were measured by grip strength. During a standardized procedure [25] patients were encouraged 'to squeeze as hard as you can' and the mean of three attempts was used in the analysis. Range of active movement of the MCP and PIP joints was measured using a finger goniometer. The mean range for the MCP and PIP joints was used in the analysis. Hand pain, during rest, activity and at night was measured using a 10-cm visual analogue scale (VAS) [26]. The Health Assessment Questionnaire (HAQ) [27], an arthritis specific scale, was used to measure performance in activities of daily living including washing, dressing and eating. Scores on eight subscales were averaged to produce a disability index, higher scores indicating greater disability. Its use in this trial was justified to assess the effects of laser on physical, and in particular, hand function.

RESULTS

Table II shows the demographic and disease characteristics of the patients studied. No significant differences between groups was noted using the Mann–Whitney two-sample test for unpaired observations. Data on the type of medication taken during the treatment period is shown in Table III.

TABLE II
The demographic and disease characteristics of the active (n = 20) and placebo (n = 20) groups

	Active group	Placebo group
Sex (M/F)	3/17	3/17
Age (yr)	67.1	60.9
(range)	(55–84)	(43–77)
Disease duration	146.4	111.6
(months)	(range: 12–396)	(range: 24–360)
Disease severity: Stage II	15	12
Stage III	5	8
Duration of hand symptoms	52.5	54.5
(months)	(range: 1–360)	(range: 5–228)
Duration of morning stiffness (min)	75.8 (19.2)	75.3 (19.3)
Grip strength (dominant hand) (mmHg)	70.5 (8.6)	96 (10.5)
Ritchie index	28 (2.7)	26.5 (2.6)
CRP	0.027 (0.01)	0.03 (0.01)
(g/ml) (upper limit <0.8)		

The mean is given in all cases (excepting sex) with the range and standard error of the mean (shown in brackets) where appropriate.

TABLE III
Type of medication taken during the treatment period by active and placebo groups

Medication	Active group		Placebo group	
	Yes	No	Yes	No
Analgesics	11	9	8	12
NSAIDs	18	2	19	1
DMARDs	13	7	16	3

Descriptive data (means and standard errors of the mean) for the subjective measures of disease activity are shown in Table IV and Fig. 1 shows histograms of the objective measures. Grip strength, MCP and PIP range of movement and the HAQ scores are shown in Fig. 2 and Table V details pain scores.

From these data few differences over time in either the active or placebo group are readily apparent. Where the differences between baseline and post-treatment scores were considered of clinical value relevant statistical tests were performed. The change score between the morning stiffness baseline value and assessment 3 (1 month at follow-up) in the active group was 39.3 min but this was not significant ($P = 0.09$) using a paired t-test. Pain during activity decreased significantly (the Wilcoxon matched pairs signed rank test was used) in both the active ($P = 0.05$) and placebo groups ($P = 0.01$) at the 3-month follow-up assessment compared to the baseline values. The change score between baseline and assessment 4 (3-month follow-up) in the placebo group for night pain, as measured on a 10-cm VAS showed an improvement of 1.7 cm which was significant at the 95% confidence level.

In terms of physical f unction tests (e.g. grip strength and range of movement) there were no differences at baseline between the treated and untreated hand. Similarly no changes were observed in the untreated hand of either group after the course of treatment.

Qualitative data on patients' perception of the effect of treatment was obtained by interview at each assessment. The overwhelming majority did not feel treatment had been effective in terms of pain reduction or functional increase. Neither the objective nor subjective data showed the treatment to be detrimental.

DISCUSSION

In this study no statistical difference was observed between the laser and placebo groups in both objective

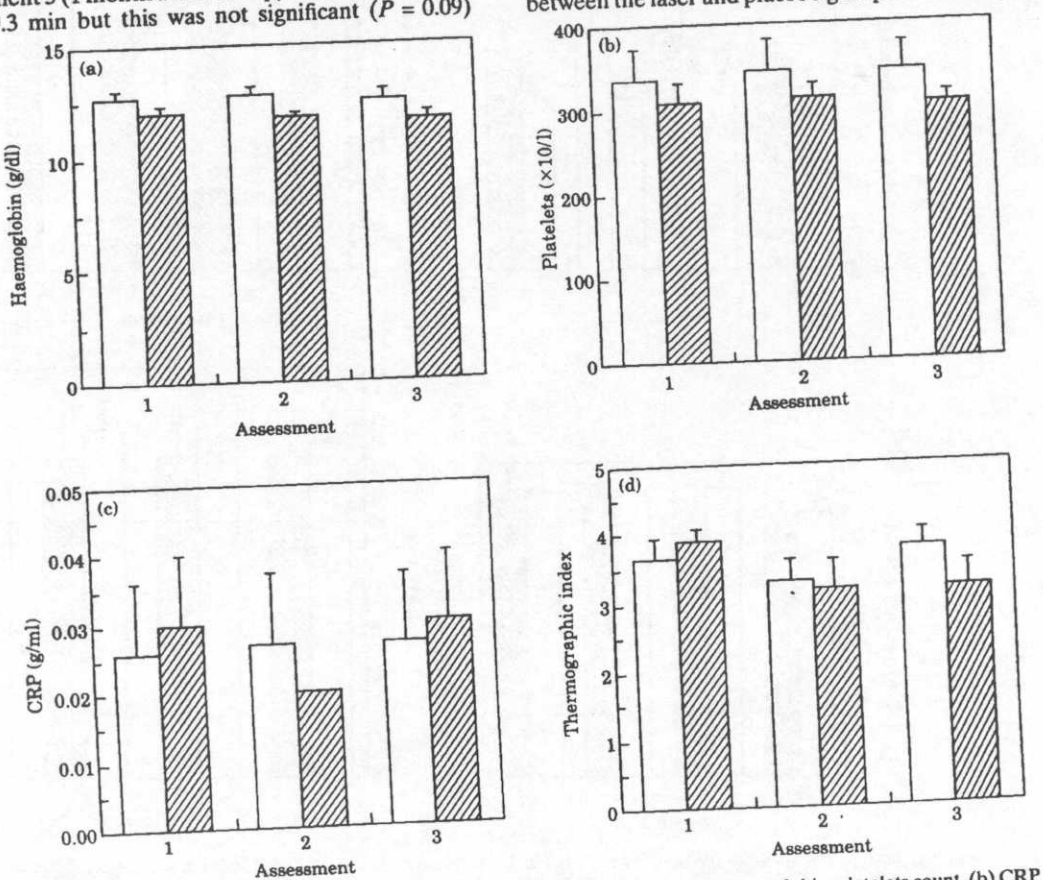

FIG. 1.—Histograms showing the means (±S.E.M.) in the active and placebo groups for (a) haemoglobin, platelets count, (b) CRP and (c) thermography assessments. (1 = baseline, $n = 20$; 2 = 1 month after treatment, $n = 20$; 3 = 3 months at follow up, $n = 13$). □, Active; ▨, placebo.

TABLE IV
Means and standard errors of the mean (in parentheses) for each of the subjective disease activity measures for the active and placebo groups at each assessment

Assessment	Active group				Placebo group			
	1 (n = 20)	2 (n = 20)	3 (n = 15)	4 (n = 13)	1 (n = 20)	2 (n = 20)	3 (n = 14)	4 (n = 13)
Morning stiffness (min)	75.8 (19.2)	57.8 (14.6)	36.5 (9.6)	70 (27.3)	75.3 (19.3)	72 (19)	86.8 (24)	47.7 (8.8)
Ritchie index	28.1 (2.7)	25 (2.8)	23.9 (3)	25.1 (3)	26.4 (2.6)	22.4 (2.3)	20.3 (2.8)	21.8 (3.5)
MCP swelling (cm)	20.3 (0.4)	20 (0.4)	19.8 (0.5)	19 (0.3)	19.8 (0.3)	19.8 (0.3)	19.7 (0.4)	19.4 (0.3)
PIP swelling (cm)	62.6 (1.3)	62.8 (1.3)	62.4 (1.5)	59.4 (1)	60.7 (1)	60.3 (1)	59.7 (1)	58.5 (1)

Assessment 1 was performed prior to the start of the trial, assessment 2 after the end of the 12 treatments, assessment 3 was after a 1 month follow-up and assessment 4 after a 3 month follow-up

and subjective outcome measures after 12 treatments or at the subsequent follow-ups.

Tables III and IV show the diminishing sample size over time and highlight some of the difficulties of this kind of research, conducted against a background of changing medical care. In total 14 patients were excluded from further data collection after the second assessment. In all cases the reason for exclusion was a

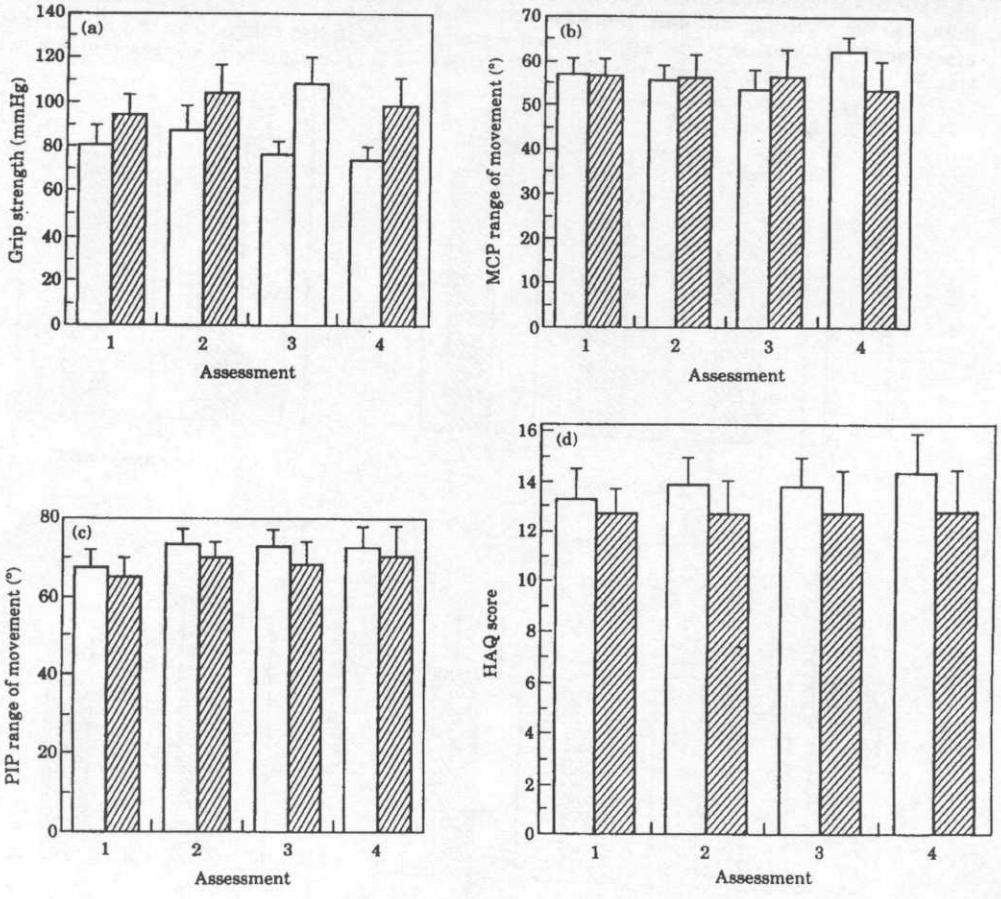

FIG. 2.—Histograms showing the means (± S.E.M.) in the active and placebo groups for (a) grip strengh, (b) MCP and (c) PIP interphalangeal range of movement and (d) Health Assessment Questionnaire over four assessments (1 = baseline, n = 20 for each group; 2 = after treatment, n = 20 for each group; 3 = 1 month at follow-up, n = 15 for the active group and 14 for the placebo; 4 = 3 months at follow-up, n = 13 for each group). □, Active; ▨, placebo.

TABLE V

Means, in cm along a 10-cm visual analogue scale, and standard errors of the mean (in brackets) for pain at rest, pain on activity and night pain for the active and placebo group over the four assessments

	Active group				Placebo group			
Assessment	1 (n = 20)	2 (n = 20)	3 (n = 15)	4 (n = 13)	1 (n = 20)	2 (n = 20)	3 (n = 14)	4 (n = 13)
Pain at rest	3.9 (0.5)	2.6 (1.9)	2.3 (0.6)	2.8 (0.8)	2.9 (0.4)	2.8 (0.5)	2.3 (0.4)	2 (0.5)
Pain on activity	5.2 (0.5)	4 (0.5)	3.9 (0.6)	3.1* (0.6)	4.3 (0.4)	4.3 (0.4)	3.8 (0.5)	2.8* (0.5)
Pain at night	2.8 (0.6)	2.5 (0.6)	2.1 (0.5)	1.8 (0.5)	3.2 (0.6)	2.5 (0.4)	2 (0.4)	1.5* (0.4)

*$P<0.05$ using the Wilcoxon ranked pairs sign match test comparing baseline to the 3-month follow-up scores.

change in drug therapy or a corticosteroid injection to any joint.

In a number of studies [8–10] LLLT has been assessed with regard to its effect on disease activity as measured by various laboratory indices including haemoglobin, platelet count and markers of the acute phase response. Palmgren *et al.* [9] showed the ESR fell significantly in the actively treated group only from 28 mm/h to 19 mm/h after 12 treatments. No changes in haemoglobin were noted. Bliddal *et al.* [10] measured haemoglobin and platelet counts but found no change following nine treatments. This study included objective markers of disease activity to compare with other studies [8, 9]. Our data failed to support the hypotheses proposed by other workers that the mechanism of action is immunomodulatory.

Goldman used Q-switch neodymium laser to one hand and sham laser to the other in 30 patients with RA [8]. He observed bilateral improvement in erythema, pain, swelling and tenderness, with the most significant improvement in the lased hand. The authors speculate on the possible rationale for bilateral improvement and suggest that the cellular effects from laser irradiation could carry over to sites distant to the treated area. For this reason the untreated hand was used as a second control in this study but no evidence was noted to suggest that the effects observed by Goldman were operative in our sample.

Despite manufacturers' claims we have found no evidence to support the use of LLLT at the parameters used for chronic RA patients with active finger joint involvement. Closer investigation of different wavelengths and energy densities would be worthwhile in an attempt to establish the clinical benefits to match those from experimental *in vitro* results [28, 29].

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ANNOUNCEMENT

VIth INTERNATIONAL CONFERENCE ON LYME BORRELIOSIS

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Further details available from: M. A. Cimmino, Cattedra di Reumatologia, Dipartimento di Medicina Interna, Universita' di Genova, Viale Benedetto XV, 6, 16 132, Genova, Italy. Tel: 39 10 353; Fax: 39 10 352 324.