FDA Cleared for Osteoarthritis of the Hand. The Effects of Low Level Laser Therapy on Osteoarthritis (OA) of the Hand. A Clinical Study

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Objective: The objective of this placebo controlled, randomized, double blind, parallel group designed clinical study was to determine the effectiveness and feasibility of over-the-counter (OTC) use of the Q Laser System, made up of the Q1000 low level laser, a multiple diode device and the 660 nm enhancer laser probe, in providing temporary relief of pain and stiffness arising from osteoarthritis of the hand, when the treatment is administered by an individual in his or her own home.

Background: Studies have shown that low level laser therapy is beneficial for treating the pain and stiffness associated with osteoarthritis when treated in medical offices 6,7,8,9,10, but there are few studies demonstrating the relief of osteoarthritis symptoms using low level laser therapy when the individual treats themselves at home.

Methods and Materials: To qualify for the study subjects had to be diagnosed with osteoarthritis of one hand by criteria set by the American College of Rheumatology. Ninety one subjects, forty six in a placebo group and forty five in an active laser group treated themselves five times every other day for 10 days for one minute each on selected proprioceptive points using the multiple diode instrument and for 30 seconds on selected acupoints and direct on the affected joints using a single diode instrument. The laser system utilized (Q Laser System manufactured by 2035 Inc) was composed of two instruments, one, a hand held DC powered laser containing eight LEDs and twelve 5 mW laser diodes arranged to form 6 direct soliton waves and 32 indirect soliton waves, emitting 2.5 J/cm² of energy to an area 1.0322 cm² covering an area of 45.7 mm in diameter. The other instrument used was a single diode 50 mW continuous beam enhancer probe operated at 35 mW emitting 2.16 J/cm² to an area 0.2826 cm² covering an area of 6 mm in diameter.

Results: ROM evaluations demonstrated 87% improvement in range of motion over the placebo group and 87% of the subjects reported at least a 30% improvement in pain as measured by the VAS scale by the end of active treatment at day 10 with continuing latent benefits of reduction of pain and improvement of range of motion at days 21 and 32. The placebo group used twice as much Tylenol, the rescue pain medication designated for this study, as did the laser treated group and 81% of the treated group were satisfied with the laser system and 95% of all subjects stated the operations and instruction manual was easy to follow and they were very confident they followed the treatment protocol.

Conclusion: Based on the results of this study it can be concluded that the protocol used with this combination of low level lasers provided substantial relief of osteoarthritis symptoms when used by the patient in their own home and the instruments were easy to use.

The Effect of Low-Level Laser in Knee Osteoarthritis: A Double-Blind, Randomized, Placebo-Controlled Trial

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Introduction: Low-level laser therapy (LLLT) is thought to have an analgesic effect as well as a biomodulatory effect on microcirculation. This study was designed to examine the pain-relieving effect of LLLT and possible microcirculatory changes measured by thermography in patients with knee osteoarthritis (KOA).

Materials and Methods: Patients with mild or moderate KOA were randomized to receive either LLLT or placebo LLLT. Treatments were delivered twice a week over a period of 4wk with a diode laser (wavelength 830nm, continuous wave, power 50mW) in skin contact at a dose of 6J/point. The placebo control group was treated with an ineffective probe (power 0.5mW) of the same appearance. Before examinations and immediately, 2wk, and 2 mo after completing...
the therapy, thermography was performed (bilateral comparative thermograph by AGA infrared camera); joint flexion, circumference, and pressure sensitivity were measured; and the visual analogue scale was recorded.

**Results:** In the group treated with active LLLT, a significant improvement was found in pain (before treatment [BT]: 5.75; 2 mo after treatment : 1.18); circumference (BT: 40.45; AT: 39.86); pressure sensitivity (BT: 2.33; AT: 0.77); and flexion (BT: 105.83; AT: 122.94). In the placebo group, changes in joint flexion and pain were not significant. Thermographic measurements showed at least a 0.5°C increase in temperature and thus an improvement in circulation compared to the initial values. In the placebo group, these changes did not occur.

**Conclusion:** Our results show that LLLT reduces pain in KOA and improves microcirculation in the irradiated area.

**Laser Acupuncture in Knee Osteoarthritis: A Double-Blind, Randomized Controlled Study**


**Objective:** The purpose of this study was to investigate the effects and minimum effective dose of laser acupuncture in knee osteoarthritis (KOA), and to determine if it is superior to placebo treatment (sham) in the evaluation of clinical-functional outcome and quality of life.

**Methods:** In this randomized, placebo-controlled study, patients with grade 2 and 3 primary KOA were selected. Group I (n = 27) received 904-nm low-level laser irradiation with 10 mW/cm² power density, 4 mW output power, 0.4 cm² spot size, 0.48 J dose per session, and 120-sec treatment time on the medial side of the knee to the acupuncture point Sp9. Group II (n = 25) received placebo-laser therapy at the same place on the same point. Patients in both of the groups had treatment 5 days per week (total duration of therapy was 10 days) and 20 min per day. The study was comprised of a 2-week (10-session) intervention. Participants were evaluated before treatment (baseline), after treatment (2nd week), and at the 12th week. In this double-blind study, a blind examiner carried out all outcome assessments. The main outcome measures were as follows: pain on movement (pVAS), 50-foot walking time (50 foot w), knee circumference (KC), medial tenderness score (MTS), Western Ontario and McMaster Universities osteoarthritis index (WOMAC), and Nottingham Health Profile (NHP).

**Results:** Statistically significant improvement was observed in PVAS, 50 foot w, and KC in group 1. In Group II, statistically significant improvement was observed in PVAS, 50 foot w, and WOMAC. When groups were compared with each other, the improvement observed in KC was superior in Group I at the 2nd week (p = 0.005). **Conclusion:** Laser acupuncture was found to be effective only in reducing periarticular swelling when compared with placebo laser.

**Infrared Diode Laser in Low Reactive-Level Laser therapy (LLLT) for Knee Osteoarthrosis**

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Degenerative joint disease (DJD), in particular in the knee, is difficult to cure successfully at present, often requiring surgical intervention. In addition, the chronic DJD patient often exhibits symptoms of both a physiological and psychological nature. A study is presented using low reactive-laser therapy (LLLT) with an 830 nm infrared continuous wave gallium aluminium arsenide (GaAlAs) diode laser, with an output power of 60 mW, in light contact laser therapy for a population of 40 patients (power density of 18 J/cm² per session) two sessions per week for eight weeks. Radiological pain score and joint mobility assessments were made before the first session, immediately after, and at 4 months after the final LLLT session. All other medication and physical therapy was discontinued at least 15 days prior to the first treatment session. Thirty-three patients (82%) reported significant removal of pain and recovery of articular joint mobility. The remaining seven patients felt there was no significant effect following LLLT, and returned to their original pretherapy medication. The side effects were minimal. LLLT is concluded to be a safe effective and noninvasive alternative to conventional surgical and medical treatment modalities for DJD patients.

**Key words** Degenerative joint disease (DJD) Laser therapy Adjunctive photochemotherapy
Efficacy of different therapy regimes of low-power laser in painful osteoarthritis of the knee: A double-blind and randomized-controlled trial

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Keywords
exercise â€“ low-power laser therapy â€“ knee osteoarthritis

Abstract

Background and Objectives
A prospective, double-blind, randomized, and controlled trial was conducted in patients with knee osteoarthritis (OA) to evaluate the efficacy of infrared low-power Gallium-Arsenide (Ga-As) laser therapy (LPLT) and compared two different laser therapy regimes.

Study Design/Materials and Methods
Ninety patients were randomly assigned to three treatment groups by one of the nontreating authors by drawing 1 of 90 envelopes labeled A (Group I: actual LPLT consisted of 5 minutes, 3 J total dose + exercise; 30 patients), B (Group II: actual LPLT consisted of 3 minutes, 2 J total dose + exercise; 30 patients), and C (Group III: placebo laser group + exercise; 30 patients). All patients received a total of 10 treatments, and exercise therapy program was continued during study (14 weeks). Subjects, physician, and data analysts were unaware of the code for active or placebo laser until the data analysis was complete. All patients were evaluated with respect to pain, degree of active knee flexion, duration of morning stiffness, painless walking distance and duration, and the Western Ontario and Mc Master Universities Osteoarthritis Index (WOMAC) at week 0, 6, 10, and 14.

Results
Statistically significant improvements were indicated in respect to all parameters such as pain, function, and quality of life (QoL) measures in the post-therapy period compared to pre-therapy in both active laser groups (P < 0.01). Improvements in all parameters of the Group I and in parameters, such as pain and WOMAC of the Group II, were more statistically significant when compared with placebo laser group P < 0.05).

Conclusions
Our study demonstrated that applications of LPLT in different dose and duration have not affected results and both therapy regimes were a safe and effective method in treatment of knee OA.


ACTION OF 904 NM DIODE LASER IN ORTHOPAEDICS AND TRAUMATOLOGY

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Objective: The semiconductor or laser diode (GaAs, 904 nm) is the most appropriate choice in painreduction therapy.

Summary Background Data: Low power density laser acts on the Prostaglandins synthesis, increasing the change of PGG2 and PGH2 Periossidos into PGI2 (also called Prostaciclyn or Endoprostol). The last one is the main product of the Arachidonic acid into the endothelial cells and into the smooth muscular cells of the vessel walls having a vasodilating and anti-inflammatory action.

Methods: Treatment was carried out on 447 cases and 435 patients (250 women and 185 men) in the period between 20.05.1987 and 31.12.1999. The patients, whose age ranged from 25 to 70, with a mean age of 45 years, were suffering from rheumatic, degenerative and traumatic pathologies as well as cutaneous ulcers. The majority of the patients had been seen by orthopaedists and rheumatologists and had undergone x-ray examination. All patients had received drug-based treatment and/or physiotherapy, with poor results. Two thirds were experiencing acute symptomatic pain, while the others presented a chronic pathology with recurrent crises. We used a pulsed diode laser, GaAs 904 nm wavelength. Frequency of treatment: 1 application per day for 5 consecutive days, followed by a 2-day interval. In the evaluation of the results the following parameters have been considered: disappearance of spontaneous and induced pain, anatomic and functional evaluation of the joints, muscular growth, verbal rating scales, hand dinamometer, patient's pain diary.

Results: Very good results were achieved especially with cases of symptomatic osteoarthritis of the cervical vertebrae, with sport-related injuries, with epicondylitis, and with cutaneous ulcers; also, last but not of least importance, with cases of osteoarthritis of the coxa.

Conclusions: Treatment with 904 nm diode laser has substantially reduced the symptoms as well as improved the quality of life of the patient, thus postponing the need for surgery.
Laser therapy is effective for degenerative osteoarthritis


In an Israeli study the effect of laser therapy in degenerative osteoarthritis (DOA) of the knee was investigated in a double blind study among 50 patients. One group received infrared (GaAlAs) and one red (HeNe) laser. Only the first group could be blinded, while the latter was open. Patients were treated twice daily, 15 minutes each time, for 10 days. The patients treated themselves after instruction. Total dose for each session was 10.3 J for red and 11.1 for infrared. Continuous mode was used for 7.5 minutes, pulsed for 7.5 minutes, rationale not stated. There was a significant pain reduction in the laser groups as compared to the placebo groups. There was no significant difference between the red and the infrared group. The Disability Index Questionnaire also revealed an improvement in the laser groups. All patients in the placebo group required analgesics within two months after laser therapy while the patients in the laser group were pain free ranging from 2 months to 1 year.

Clinical efficacy of low power laser therapy in osteoarthritis.

Review article: Marks R, de Palma F.

Of the various physical interventions used to relieve the symptoms of osteoarthritis, a common degenerative joint disease causing considerable pain and disability, low power laser therapy has been reported to be extremely successful in Russia and Eastern Europe. Although the overall number of studies was small, this literature review and analysis highlights the relevant controlled clinical trials and related basic research in English-language publications. This review indicates that, despite their shortcomings, the six studies analysed did report post-treatment improvements in a variety of osteoarthritic problems, including pain, mobility, tenderness and function, with few adverse effects. Possible mechanisms documented for the observed results included peripheral nerve stimulation, resolution of inflammation, enhanced chondrocyte proliferation and increased matrix synthesis. Not all studies were affirmative and few detailed how reliable their measurements were. Clearly, much more work is needed in this area.

THE EFFECT OF LOW POWER LASER THERAPY ON OSTEARTHRITIS OF THE KNEE

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Treatment was performed on 20 patients, aging from 42 to 60 years. All patients had received conservative treatment with poor results. Laser device used for this treatment was pulsed IR diode laser; 810 nm wavelength once per day for 5 consecutive days, followed by a 2-day interval. The total number of applications was 12 sessions. Irradiation was performed on 5 periarticular tender points, each for 2 min. The treatment outcome (pain relief and functional ability) was observed and measured according to the following methods: 1) Numerical rating scales (NRS), 2) Self assessment by the patient, 3) Index of severity for osteoarthritis of the knee (ISK), 4) Analgesic requirements. We achieved significant improvement in pain relief and quality of life in 70% of patients, comparing to their previous status (p < 0.05). There was no significant change in range of motion of the knee.

Low-level laser therapy in osteoarticular diseases in geriatric patients


INTRODUCTION: Laser light absorption through the skin causes tissue changes, targeting the nervous, the lymphatic, the circulatory and the immune systems with an antalgic, anti-inflammatory, anti-edemic effect and stimulating tissue repair. Therefore low level laser therapy is now commonly used in numerous rehabilitation centers, including the "Istituto Gerontologico Pio Albergo Trivulzio", Milan, Italy. However, to activate the treatment program, the basic medical research results must always be considered to choose the best optical wavelength spectrum, technique and dose, for rehabilitative laser therapy. We analyzed the therapeutic effects of different wavelengths and powers in various treatment schedules. In particular, a protocol was designed to test such physical parameters as laser type, doses and individual schedule in different pathologic conditions. We report the results obtained with low level laser therapy in the rehabilitation of geriatric patients, considering the various physical and technical parameters used in our protocol.

MATERIAL AND METHODS: We used the following laser equipment: an HeNe laser with 632.8 nm wavelength (Mectronic), a GaAs Laser with 904 nm wavelength (Mectronic) and a CO2 Laser with 10,600 nm wavelength (Etoile). To evaluate the patient clinical status, we use a different form for each involved joint; the laser beam is targeted on the region of interest and irradiation is carried out with the sweeping method or the points technique. Irradiation technique, doses and physical parameters (laser type, wavelength, session dose and number) are indicated on the form. The
complete treatment cycle consists of 5 sessions per week—20 sessions in all. At the end of the treatment cycle, the results were scored on a 5-grade semiquantitative scale—excellent, good, fair, poor and no results. We examined 3 groups of patients affected with gonarthrosis (149 patients), lumbar arthrosis (117 patients), and algodystrophy (140 patients) respectively.

RESULTS: In gonarthrosis patients, the statistical analysis of the results showed no significant differences between CO2 laser and GaAs laser treatments \( (p = .975) \), but significant differences between CO2 laser and HeNe laser treatments \( (p = .02) \) and between GaAs laser and HeNe laser treatments \( (p = .003) \). In lumbar arthrosis patients treated with GaAs or HeNe laser, significant differences were found between the two laser treatments and the combined sweeping-points techniques appeared to have a positive trend relative to the sweeping method alone, especially in sciatic suffering. In the algodystrophy syndrome, in hemiplegic patients, significant differences were found between CO2 and HeNe laser treatments \( (p = .026) \), between high and low CO2 laser doses \( (p = .024) \), and between low CO2 laser dose and high HeNe laser dose \( (p = .006) \).

CONCLUSIONS: Low level laser therapy can be used to treat osteoarticular pain in geriatric patients. To optimize the results, the diagnostic picture must be correct and a treatment program defining the physical parameters used (wavelength, dose and irradiation technique) must also be designed.

Low level laser therapy (classes I, II and III) for the treatment of osteoarthritis.

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BACKGROUND: Osteoarthritis (OA) affects a large proportion of the population. Low Level Laser Therapy (LLLT) is a light source that generates extremely pure light, of a single wavelength. The effect is not thermal, but rather related to photochemical reactions in the cells. LLLT was introduced as an alternative non-invasive treatment for OA about 10 years ago, but its effectiveness is still controversial.

OBJECTIVES: To assess the effectiveness of LLLT in the treatment of OA.

SEARCH STRATEGY: We searched MEDLINE, EMBASE, the Cochrane Musculoskeletal registry, the registry of the Rehabilitation and Related Therapies field and the Cochrane Controlled Trials Register up to January 30, 2000.

SELECTION CRITERIA: Following an a priori protocol, only controlled clinical trials of LLLT for the treatment of patients with a clinical diagnosis of OA were eligible. Abstracts were excluded unless further data could be obtained from the authors.

DATA COLLECTION AND ANALYSIS: Two reviewers independently selected trials and abstracted data using predetermined forms. Heterogeneity was tested with Cochran’s Q test. A fixed effects model was used throughout for continuous variables, except where heterogeneity existed, in which case, a random effects model was used. Results were analyzed as weighted mean differences (WMD) with 95% confidence intervals (CI), where the difference between the treated and control groups was weighted by the inverse of the variance. Standardized mean differences (SMD) were calculated by dividing the difference between treated and control by the baseline variance. SMD were used when different scales were used to measure the same concept (e.g. pain). Dichotomous outcomes were analyzed with odds ratios.

MAIN RESULTS: Five trials were included, with 112 patients randomized to laser, 85 patients to placebo laser. Treatment duration ranged from 4 to 10 weeks. Pain was assessed by four trials. The pooled estimate (random effects) of three trials showed no effect on pain measured using a scale \( (SMD: -0.2, 95\% CI: -1.0, +0.6) \), but there was statistically significant heterogeneity \( (p>0.05) \). Two of the trials showed no effect and one demonstrated very beneficial effects with laser. In another trial, with no scale-based pain outcome, significantly more patients reported pain relief (yes/no) with laser with an odds ratio of 0.05, \( (95\% CI: 0.0 \text{ to } 1.56) \). Other outcomes of joint tenderness, joint mobility and strength were not significant.

REVIEWER’S CONCLUSIONS: For OA, the results are conflicting in different studies and may depend on the method of application and other features of the LLLT application. Clinicians and researchers should consistently report the characteristics of the LLLT device and the application techniques used. New trials on LLLT should make use of standardized, validated outcomes. Despite some positive findings, this meta-analysis lacked data on how LLLT effectiveness is affected by four important factors: wavelength, treatment duration of LLLT, dosage and site of application over nerves instead of joints. There is clearly a need to investigate the effects of these factors on LLLT effectiveness for OA in randomized controlled clinical trials.
Improvement of pain and disability in elderly patients with degenerative osteoarthritis of the knee treated with narrow-band light therapy.


In an Israeli study the effect of laser therapy in degenerative osteoarthritis (DOA) of the knee was investigated in a double blind study among 50 patients. One group received infrared (GaAlAs) and one red (HeNe) laser. Only the first group could be blinded, while the latter was open. Patients were treated twice daily, 15 minutes each time, for 10 days. The patients treated themselves after instruction. Total dose for each session was 10.3 J for red and 11.1 for infrared. Continuous mode was used for 7.5 minutes, pulsed for 7.5 minutes, rationale not stated. There was a significant pain reduction in the laser groups as compared to the placebo groups. There was no significant difference between the red and the infrared group. The Disability Index Questionnaire also revealed an improvement in the laser groups. All patients in the placebo group required analgesics within two months after laser therapy while the patients in the laser group were pain free ranging from 2 months to 1 year.