

Low power laser treatment in patients with knee osteoarthritis

Funda Tascioglu, Onur Armagan, Yildiray Tabak, Ilker Corapci, Cengiz Oner

Osmangazi University, Faculty of Medicine, Department of Physical Therapy and Rehabilitation, Eskisehir, Turkey

Summary

The aim of this study was to investigate the analgesic efficacy of low power laser therapy in patients with knee osteoarthritis (OA). The study design was randomised, placebo-controlled and single blinded. Sixty patients with knee OA according to the American College of Rheumatology criteria were included and randomly assigned to three treatment groups: active laser with dosage of 3J/per painful point, active laser with a dosage of 1.5J per painful point and placebo laser treatment groups. A Gal-Al-As diode laser device was used as a source of low power laser with a power output of 50 mW and a wavelength of 830 nm. The patients were treated 5 times weekly with 10 treatments in all. The clinical assessments included Western Ontario and McMaster Universities os-

teoarthritis index (WOMAC) pain, stiffness and physical function subscales. In addition, the intensity of pain at rest and on activation was evaluated on a visual analogue scale. Compared to baseline, at week 3 and at month 6, no significant improvement was observed within the groups. Similarly, no significant differences were found among the treatment groups at any time.

With the chosen laser type and dose regimen the results that we obtained in this study, suggest that low-level laser therapy has no effect on pain in patients with knee OA.

Key words: low-power laser therapy; knee osteoarthritis

Introduction

Osteoarthritis (OA) of the knee is the most common joint disease in the elderly and is associated with significant physical disability [1, 2]. The treatment of knee OA is mainly aimed at alleviation of pain. Although non-steroidal anti-inflammatory drugs (NSAIDs) are widely used to treat the pain and stiffness associated with knee OA, the high incidence of serious upper gastrointestinal side effect with NSAIDs can limit their use [3]. To avoid or to reduce the side effects associated with NSAIDs, physical therapy agents such as ultrasound, transcutaneous electrical nerve stimulation therapy and muscle strengthening exercises are frequently used [4–7].

Low-power laser therapy has been used to control pain in different musculoskeletal conditions. Despite its widespread use, the results of the experimental and clinical studies are conflicting. The results of some placebo-controlled studies suggest that low-power laser treatment may be useful for reducing the pain in cervical osteoarthritis [8] and medial and lateral epicondy-

litis [9]. On the other hand, a number of placebo-controlled, randomised and double blind studies have not been able to demonstrate any significant or convincing clinically relevant effects over placebo in the treatment of lateral epicondylitis [10], rotator cuff tendinitis [11] and rheumatoid arthritis [12]. However, very few controlled clinical studies of low-power laser applied for the treatment of knee OA have been reported and the findings from these studies are also contradictory [13, 14]. The results obtained from the trial of Stelian *et al.* suggest that laser treatment may be useful in reducing the pain and disability associated with knee OA [13]. In contrast, in a double blind, placebo controlled study Bülow *et al.* detected no difference between the actively and the placebo treated groups [14].

Since the results of low power laser therapy effectiveness studies in knee OA show considerable variation, we aimed to evaluate the effect of low power laser treatment in patients with knee OA in the present study.

Material and methods

Patients

The study was carried out at the Physical Therapy and Rehabilitation Department of Osmangazi University Hospital. Sixty ambulant patients who had idiopathic knee OA according to American College of Rheumatology criteria were recruited for the study [15]. All patients had Grade II to III bilateral knee OA confirmed radiologically according to the Kellgren-Lawrence grading system [16].

Exclusion criteria included Kellgren-Lawrence Grade I and IV radiological changes, knee joint disease other than OA, OA of the hip joint, osteoarthritic involvement of the foot joints, serious concomitant systemic diseases, intra-articular fluid effusion, previous physical therapy and intra-articular corticosteroid or hyaluronic acid injections during the last six months. None of the patients had previously undergone knee surgery.

The patients were briefed about the study and written consent was obtained from all patients.

Study design

This study was designed as a prospective, randomised, placebo-controlled and single-blinded study with a six month follow-up period and it was approved by the ethics committee of the Osmangazi University Medical Faculty.

Randomisation

Sixty patients, who fulfilled the entry criteria, were admitted to the study and they were randomly divided into three groups using numbered envelopes. Each group consisted of 20 patients.

Treatments

The treatment was applied to both sides of the knee. As a source of low power laser, a Gal-Al-As diode laser device (Endolaser 476, Enraf Nonius, Netherlands) was used with a power output of 50 mW and a wavelength of 830 nm. The diameter of the laser beam at the treatment point was 1 mm. The laser was set to deliver a continuous form of energy. In all patients, five painful points, which were found on clinical examination, were chosen. In the first group, a two minute irradiation at each point (a total of 10 minutes) was considered as one irradiation dose. The dose per tender joint was 3 joule. The total dose per treatment was 15 joule and the accumulated dose for ten treatments 150 joule.

Twenty patients in the second group were treated with the same low power laser treatment design, but the painful points were irradiated for a duration of one minute (a total of 5 minutes). The dose per tender joint was 1.5 joule. The total dose per treatment was 7.5 joule and the accumulated dose for ten treatments was 75 joule.

The patients in the third group were treated with

placebo laser. For the placebo laser application, the same laser device seemed to be working but with no laser beams transferring to the treated area and five painful points were irradiated.

All treatments were applied once a day, five days a week for a total duration of 10 days. All patients were treated by the same physician.

Clinical assessment

A blinded physician unaware of the treatment allocation performed the clinical assessments at baseline, at week 3 and at month 6.

Pain, functional capacity and stiffness were evaluated by Western Ontario and McMaster universities osteoarthritis index (WOMAC) [17]. The WOMAC is a validated disease specific self-report questionnaire and is based on Likert scales [18]. This index consists of 3 subscales (5 questions on pain, 2 questions on stiffness and 17 questions on functional status) and is the standard for assessment and monitoring of knee OA. The total score ranges from 0 (best) to 96 (worst).

In addition to the WOMAC subscale for pain, the patient's pain at rest and on activation was assessed using a 100 mm visual analogue scale (0: no pain, 100: worst pain).

Patients were allowed to take paracetamol (to a maximum of 2 gm daily) during the study period and they were told to inform us about their medication schedule.

Laboratory assessment

Laboratory assessment was performed only at baseline and included routine haematological and blood biochemistry tests.

Statistical analysis

After assessing the normal distribution of the data, baseline characteristics of the treatment groups were compared using one-way analysis of variance for independent samples and chi-square test for homogeneity of proportions, as appropriate.

Analysis of covariance (ANCOVA) was used to test for changes in the three domains of the WOMAC osteoarthritis index, rest pain and activation pain values between the three periods in each group with the baseline scores as covariates. The consumption of paracetamol was analysed using chi-square test. In addition, a logistic regression analysis (Hosmer-Lemeshow analysis) was performed with the paracetamol use at baseline as a covariate. Continuous variables were summarized as mean and the standard deviations were given in parenthesis. Differences with P values ≤ 0.05 were considered statistically significant and all results are expressed with 95% confidence interval. All analyses were performed by using the SPSS 11.5 for Windows software program.

Results

Sixty patients with knee OA (43 women, 17 men) aged between 49–72 years were included in the trial and all of them completed the study period. There were no significant differences in the baseline characteristics of the 60 patients randomised in the study (table 1).

WOMAC scores for pain, stiffness and physical function were similar in all groups at baseline.

Compared to baseline, at week 3 and at month 6, only insignificant, small improvements were observed in each group. The difference among the three treatment groups for WOMAC scores was at no time statistically important. (table 2).

As shown in table 3, VAS scores for rest and activation pain were not different at baseline when we compared the three groups. As compared to the

baseline, we found no significant improvement within each group at week 3 and at month 6. In comparing the changes on VAS scores among the groups, no significant difference was observed.

At baseline, paracetamol consumption was similar in both groups. The number of the patients using paracetamol during the treatment and follow-up periods was also very similar in all groups

and there was no significant difference among the groups (table 4). The results of the logistic regression analysis (Hosmer-Lemeshow analysis) showed that the baseline variables have no effect on the paracetamol use.

No systemic or local side effects were reported during or after the treatment period.

Table 1

Baseline characteristics of the patients.

	Active laser (3 J/point) (N = 20)	Active laser (1.5 J/point) (N = 20)	Placebo laser (N = 20)
Age (year)	62.86 (7.32)	59.92 (7.59)	64.27 (10.55)
Disease duration (year)	7.92 (5.12)	6.36 (4.21)	7.05 (6.53)
Body mass index (kg/cm ²)	27.56 (5.65)	28.63 (6.48)	29.56 (9.54)
Gender (Female/Male)	14/6	15/5	13/7
KL radiological grade (II/III)*	12/8	10/10	11/9

* KL: Kellgren-Lawrence (Numbers 12, 10, and 11 indicates the patient number with a radiological grade II, numbers 8, 10 and 9 indicates patient number with a radiologic grade III according to Kellgren-Lawrence).

Table 2

Baseline and the follow-up results of Western Ontario and McMaster Universities osteoarthritis index (WOMAC) pain, stiffness and physical function scores of the patients.

	Pre-treatment Mean (SD) (95% CI)*	Week 3 Mean (SD) (95% CI)	Month 6 Mean (SD) (95% CI)
WOMAC pain			
Active laser (3 J)	10.28 (3.56) (9.09–11.40)	10.20 (2.58) (8.99–11.31)	10.44 (3.03) (9.00–11.80)
Active laser (1.5 J)	11.60 (4.81) (9.89–11.80)	10.88 (3.51) (9.55–11.45)	11.28 (2.41) (9.00–11.79)
Placebo laser	9.56 (3.88) (8.83–10.47)	9.27 (4.41) (8.61–10.19)	9.86 (3.56) (9.03–10.77)
WOMAC stiffness			
Active laser (3 J)	4.12 (3.01) (3.26–5.04)	4.00 (2.05) (3.03–4.97)	3.92 (1.80) (3.08–4.82)
Active laser (1.5 J)	4.64 (1.89) (4.04–5.16)	4.72 (1.69) (4.02–5.38)	4.48 (1.56) (3.91–4.99)
Placebo laser	4.45 (2.51) (3.60–5.30)	4.38 (1.77) (3.62–5.18)	4.23 (2.05) (3.39–5.11)
WOMAC function			
Active laser (3 J)	36.60 (7.09) (33.46–39.04)	35.04 (8.38) (32.70–38.10)	34.84 (8.86) (31.04–37.96)
Active laser (1.5 J)	37.96 (9.67) (33.84–41.26)	36.00 (10.14) (32.59–40.41)	38.52 (10.49) (35.47–41.93)
Placebo laser	39.46 (12.56) (35.67–43.32)	37.53 (10.08) (33.61–41.49)	38.66 (9.65) (34.47–42.83)

* CI: Confidence interval

Table 3

Pain intensity at rest and on activation by visual analogue scale.

	Pre-treatment Mean (SD) (95% CI)*	Week 3 Mean (SD) (95% CI)	Month 6 Mean (SD) (95% CI)
Pain intensity at rest			
Active laser, (3 J/point)	39.08 (14.86) (33.51–44.49)	36.84 (14.79) (31.58–42.82)	38.68 (14.87) (32.49–43.81)
Active laser, (1.5 J/point)	41.55 (16.65) (36.69–46.21)	38.12 (10.48) (32.88–43.32)	40.02 (9.11) (35.19–45.01)
Placebo laser	37.92 (11.00) (33.77–42.03)	35.95 (16.48) (32.22–41.37)	38.94 (15.05) (34.79–43.01)
Pain intensity on activation			
Active laser, (3 J/point)	68.00 (15.45) (61.94–74.16)	64.96 (13.05) (59.72–70.18)	66.84 (13.54) (61.41–72.19)
Active laser, (1.5 J/point)	65.72 (18.68) (57.46–71.64)	60.28 (15.41) (53.27–67.33)	61.84 (12.90) (56.76–66.94)
Placebo laser	63.88 (16.07) (55.71–72.09)	59.76 (18.45) (51.93–67.57)	62.04 (16.66) (54.77–69.33)

* CI: Confidence interval

Table 4

Number of the patients receiving paracetamol at baseline, week 3, and month 6.

	Baseline	Week 3	Month 6
Active laser, 3 J/joint	13	12	12
Active laser, 1.5 J/joint	12	13	13
Placebo laser	12	11	12

Discussion

In this study we aimed to evaluate the effect of low power laser treatment on knee OA, one of the most common painful conditions in rheumatology practice. The results obtained showed that no statistical difference was observed between the active laser treatments given at two different dosages and the placebo group after 10 treatments or at the follow-up.

The usefulness of low power laser therapy in knee OA has been subjected to only limited study and the results of these studies are conflicting. In 1992, Stelian *et al.* randomly assigned 50 patients with knee OA to receive treatment with red (wavelength, 630 nm), infrared (830 nm) or placebo laser light emitters [13]. Treatment was applied on both sides of the knee twice daily for 10 days and every treatment was composed of 7.5 minutes of continuous wave application and 7.5 minutes of pulse treatment. Total delivered energy was similar for the red emitters (10.3 J) and the infrared emitters (11.1 J). They observed significant functional improvement and pain reduction in the red and infrared groups but not in the placebo group. On the basis of these findings, they concluded that low power laser therapy is effective in pain relief and improvement of functional ability. Although we used a similar laser device and the same wavelength as Stelian, the differences in treatment frequency (twice a day), total dosage and efficacy variables might explain the differences between Stelian's study and the present trial. In another double blind, placebo controlled study, Bülow *et al.* used a Ga-Al-As infrared laser with a wavelength 830 nm in the treatment of knee OA [14]. The results of this study showed that there were no statistically significant differences between laser and placebo treated groups for any measures of pain, strength and joint mobility. Based on these results, the author suggested that low power lasers should not be used as routine treatment before more scientific evidence documenting any beneficial effects is available.

Our results are similar to those reported by Bülow *et al.* In spite of some differences in design, we used the same type of laser and the same wavelength, and chose to use a dosage close to one used in Bülow's study (1.5–4.5 J/per painful joint). Therapy duration in this study was also similar to Bülow's study in which 9 sessions of laser therapy were applied in knee OA.

Previous studies of the analgesic effects of low level laser applications in musculoskeletal disorders have yielded conflicting results. There are reports of useful pain relief [8, 9] amongst growing evidence of a significant placebo action [10–12]. This controversy may be related to various factors. Different lasers may have different effectiveness in different diagnoses and parameters such as wavelength, duration of treatment, energy density, number of treatments and mode of delivery may be important [19]. In the evaluation of a therapy,

it is often difficult to determine the optimal dosage and treatment schedule. For laser therapy, the minimal effective dosage is in most cases unknown. An additional question is which wavelength will be optimal [20]. There is little evidence in the literature giving clues to the optimal dosage of laser energy with regard to intensity, frequency, wavelength and peak pulse on the one hand and to the various pathological conditions on the other [21]. The findings of the clinical studies must be interpreted against this background.

The exact mechanism of pain reduction by laser therapy is not understood. Different experimental studies suggest that low power laser therapy has anti-inflammatory and analgesic effects [22–24]. In another study, the authors have suggested that neuronal activity inhibition might be responsible for the therapeutic effect and that the laser irradiation selectively inhibited nociceptive signals at peripheral nerves [25]. The results of these experimental studies are also affected by various factors such as the condition of the subjects, the characteristic of the laser (wavelength, dosage, pulse), the irradiated areas and the application time and period and it is possible that unknown mechanisms may be involved in the pain reduction following low power laser treatment [22].

In this study, however, we found no statistical difference between the laser and placebo groups in all outcome measures after 10 treatments or at the subsequent follow-up. This failure in pain reduction may be due to the laser modality, dosages and wavelength selection used in this trial. Since the penetration of laser irradiation into the skin is limited to a few millimetres, only very small joints can be treated with any sensible theoretical background [26]. For this reason it is also possible that laser therapy is ineffective in patients with knee OA.

In conclusion, the results of this study indicate that low power laser, given at two different dosages, does not play a significant role in reducing pain in the treatment of knee OA. Different lasers may have a different effectiveness in different diagnoses. Although we did not find any statistically significant differences between the active and placebo groups in the present study, we cannot exclude the possibility of efficacy with another regimen and we believe that further well designed clinical trials are needed.

Correspondence:

Dr. Funda Tascioglu
Osmangazi University
Faculty of Medicine
Department of Physical Therapy
and Rehabilitation
Meselik Campus
TR-26480 Eskisehir
E-Mail: fbatmaz@superonline.com

References

- 1 Felson DT, Zhang Y, Hannan MT, Naimark A, Weissman BN, Aliabadi P, et al. The incidence and natural history of knee osteoarthritis in the elderly. The Framingham Osteoarthritis Study. *Arthritis Rheum* 1995;38:1500–5.
- 2 Felson DT. The course of osteoarthritis and factors that affect it. *Rheum Dis Clin North Am* 1993;19:607–15.
- 3 Scheiman JM. Gastrointestinal toxicity caused by non-steroidal anti-inflammatory drugs (NSAIDs) is the most frequent drug side effect in the United States. *Gastroenterol Clin North Am* 1996;25:279–98.
- 4 Cheing GL, Hui-Chan CW, Chan KM. Does four weeks of TENS and/or isometric exercise produce cumulative reduction of osteoarthritic knee pain? *Clin Rehabil* 2002;16:749–60.
- 5 Talbot LA, Gaines JM, Ling SM, Metter EJ. A home-based protocol of electrical muscle stimulation for quadriceps muscle strength in older adults with osteoarthritis of the knee. *J Rheumatol* 2003;30:1571–8.
- 6 Kozanoglu E, Basaran S, Guzel R, Guler-Uysal F. Short term efficacy of ibuprofen phonophoresis versus continuous ultrasound therapy in knee osteoarthritis. *Swiss Med Wkly* 2003;14:333–8.
- 7 Deyle GD, Henderson NE, Matekel RL, Ryder MG, Garber MB, Allison SC. Effectiveness of manual physical therapy and exercise in osteoarthritis of the knee. A randomised, controlled trial. *Ann Intern Med* 2000;132:173–81.
- 8 Ozdemir F, Birtane M, Kokino S. The clinical efficacy of low-power laser therapy on pain and function in cervical osteoarthritis. *Clin Rheumatol* 2001;20:181–4.
- 9 Simunovic Z, Trobonjaca T, Trobonjaca Z. Treatment of medial and lateral epicondylitis-tennis and golfer's elbow-with low laser therapy: a multicenter double-blind, placebo-controlled study on 324 patients. *J Clin Laser Med Surg* 1998;16:145–51.
- 10 Haker EH, Lundeberg TC. Lateral epicondylalgia. Report of noneffective midlaser treatment. *Arch Phys Med Rehabil* 1991;72:984–8.
- 11 Vecchio P, Cave M, King V, Adebajo AO, Smith M, Hazleman BL. A double-blind study of the effectiveness of low-level laser treatment of rotator cuff tendinitis. *Br J Rheumatol* 1993;32:740–2.
- 12 Goats G, Flett E, Hunter JA, Stirling A. Low intensity laser and phototherapy for rheumatoid arthritis. *Physiotherapy* 1996;82:311–20.
- 13 Stelian J, Gil I, Habot B, Rosenthal M, Abramovici I, Kutok N, et al. Improvement of pain and disability in elderly patients with degenerative osteoarthritis of the treated with narrow-band light therapy. *J Am Geriatr Soc* 1992; 40:23–6.
- 14 Bülow PM, Hensen J, Danneskiold-Samsøe B. Low power Ga-Al-As laser treatment of painful osteoarthritis of the knee. *Scand J Rehab Med* 1994;26:155–9.
- 15 Altman R, Asch E, Bloch D, Bole G, Borenstein D, Brandt K, et al. Development of criteria for the classification and reporting of osteoarthritis. *Arthritis Rheum* 1986;29:1039–49.
- 16 Kellgren JH, Lawrence JS. Radiological assessment of osteoarthritis. *Ann Rheum Dis* 1957;16:494–501.
- 17 Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, et al. Validation study of WOMAC: A health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip and knee. *J Rheumatol* 1988;15:1833–40.
- 18 Bellamy N, Kean WF, Buchanan WW, Gerez-Simon E, et al. Double-blind randomised controlled trial of sodium meclofenamate (Meclofen) and diclofenac sodium (Voltaren): post validation reapplication of the WOMAC Osteoarthritis Index. *J Rheumatol* 1992;19:153–9.
- 19 Basford JR, Sheffield PT, Mair SD, Ilstrup DM. Low-energy helium neon laser treatment of thumb osteoarthritis. *Arch Phys Med Rehabil* 1987;68:794–97.
- 20 Beckerman H, de Bie RA, De Cuyper HJ, Oostendorp RAB. The efficacy of laser therapy for musculoskeletal and skin disorders: a criteria-based meta-analysis of randomised clinical trials. *Physical Therapy* 1992;7:483–91.
- 21 Vasseljen O, Hoeg N, Kjeldstad B, Johnson A, Larsen S. Low-level laser versus placebo in the treatment of tennis elbow. *Scand J Rehab Med* 1992;24:37–42.
- 22 Honmura A, Ishii A, Yanase M, Obata J, Haruki E. Analgesic effect of Ga-Al-As diode laser irradiation on hyperalgesia in carrageenin-induced inflammation. *Lasers Surgery Med* 1993;13:463–9.
- 23 Walker J. Relief from chronic pain by low power laser irradiation. *Neurosci Lett* 1983;43:339–44.
- 24 Coderre TJ, Katz J, Vaccarino AL, Mezlak R. Contribution of central neuroplasticity to pathological pain: review of clinical and experimental evidence. *Pain* 1993;52:259–85.
- 25 Jarvis D, MacIver B, Tanelian DL. Electrophysiologic recording and thermodynamic modelling demonstrate that helium-neon laser irradiation does not affect peripheral Ad- or C-fiber nociceptors. *Pain* 1990;43:235–42.
- 26 King PR. Low level laser therapy: a review. *Laser Med Sci* 1989;4:141–50.