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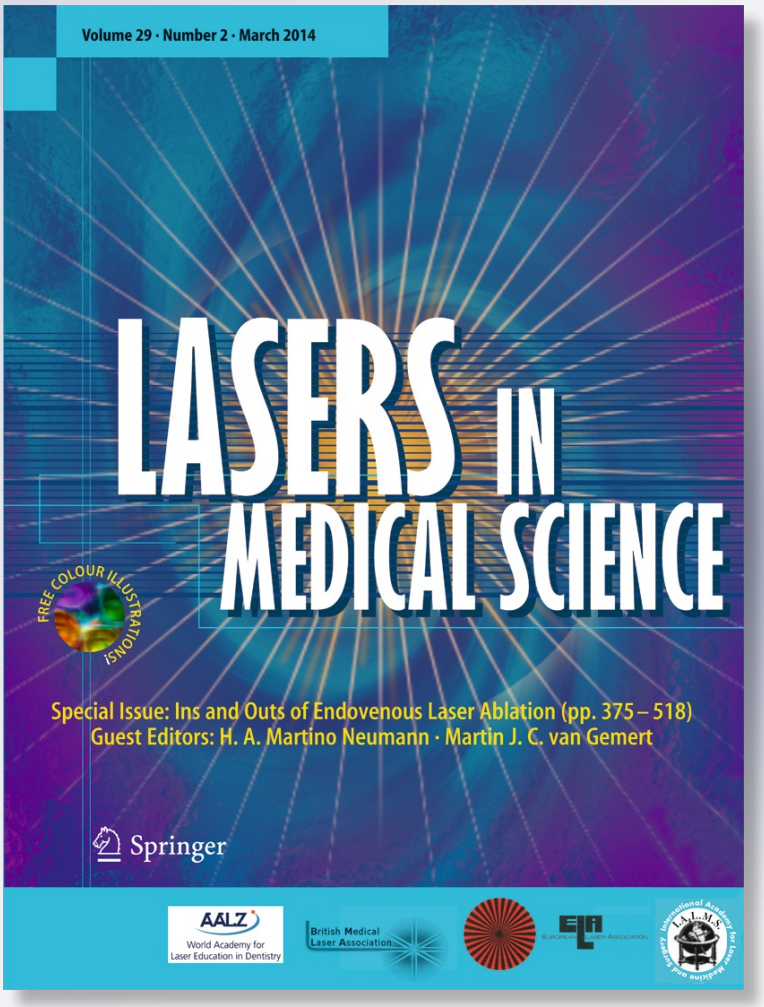

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ORIGINAL ARTICLE

Effect of low-level laser therapy in patients with chronic knee osteoarthritis: a single-blinded randomized clinical study

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Abstract The aim of this study was to investigate the effect of low-level laser therapy (LLLT) on pain relief and functional performance in patients with chronic knee osteoarthritis (OA). Forty patients with knee OA were randomly assigned into active laser group (n=20) and placebo laser group (n=20). The LLLT device used was a Ga–As diode laser with a power output of 50 mW, a wavelength of 850 nm, and a diameter beam of 1 mm. Eight points were irradiated and received dosage of 6 J/point for 60 s, with a total dosage of 48 J/cm^2 in each session. The placebo group was identical but treated without emission of energy. LLLT was applied two times per week over the period of 4 weeks. Outcome measurements included pain intensity at rest and at movement on visual analog scale, knee function using Western Ontario McMaster Universities Osteoarthritis Index scale, and ambulation duration. These measurements were collected at baseline and post-intervention. The results showed significant improvements in all assessment parameters in both groups compared to baseline. Active laser group showed significant differences in pain intensity at rest and movement, knee function, and ambulation duration when compared with the placebo group. Therefore, LLLT seemed to be an effective modality for short-term pain relief and function improvement in patients with chronic knee OA.

Keywords Low-level laser therapy · Knee · Osteoarthritis · Pain

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Introduction

Osteoarthritis (OA) is a degenerative joint disease characterized by progressive loss of articular cartilage and reflected clinically by pain, restricted range of motion, and muscle weakness. These can cause difficulties in the daily living activities and impaired quality of life [1, 2].

Osteoarthritis is a major health problem presenting to the primary care physicians in Saudi Arabia, and its incidence tends to increase affecting middle-aged and elderly with associated higher rate of obesity [3–6].

The therapeutic options for OA include pharmacological and nonpharmacological modalities. These are directed to relief of pain and inflammation, and improving function and quality of life. The former treatments include nonsteroidal anti-inflammatory drugs (NSAIDs) that are widely prescribed for treatment of OA. However, their use is directly associated with various side effects, especially on the gastrointestinal tract, particularly in elderly making the treatment unsustainable. Moreover, NSAIDs may provide only partial pain relief for many

patients with OA [7]. Therefore, nonpharmacological treatments must be preferred as the first-line therapy, especially in the elderly. Nonpharmacologic treatments include patient education, weight reduction [8], electrical stimulation [9], manual therapy and strengthening exercises [10], ultrasound [11], orthotic devices [12], and low-level laser therapy (LLLT) [13].

LLLT has been used successfully to control pain in the wide range of musculoskeletal disorders. Many authors have suggested that LLLT may be useful for reducing pain in acute and chronic conditions such as cervical osteoarthritis [13], medial and lateral epicondylitis [14], and low-back pain [15]. However, some studies have not been able to demonstrate any significant or convincing clinical effect in painful musculoskeletal conditions [16–20].

Recent meta-analysis has found that LLLT administered within optimal dosage levels, within the 2–4-week treatment regimen, introduce clinically relevant pain relief compared to placebo controls [21]. Moreover, Hegedus et al. observed a significant decrease in pain, reduction of knee circumference, and improved microcirculation as compared to the placebo group treated with a sham laser [13]. However, a systematic review by Brosseau et al. [22] concluded that the results were conflicting in different studies and may depend on the method of application, including wavelength, treatment duration, dosage, and site of application over the joints. Since the results of LLLT studies on the knee, OA showed considerable variation, and the findings are contradictory [13, 21, 22]. Therefore, the aim of this single-blinded randomized study was to investigate the effects of LLLT on pain relief and functional performance in patients with chronic knee OA.

Material and methods

Subjects

This study was designed as a single-blinded randomized clinical trial, and it was carried out in the physical therapy department, King Saud Medical City, Riyadh, Saudi Arabia.

Patients with following criteria had been enrolled in the study: (1) knee OA according to American College of Rheumatology criteria [23]; (2) knee OA of grade II or III according to the Kellgren–Lawrence grade [24]; (3) had a minimum score of 25 on the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) total score; (4) knee pain ≥4 on visual analog scale (VAS) in the previous 3 months; and (5) willingness to participate and follow the treatment schedule. The patients were excluded if they had concomitant disease affecting the knee (such as rheumatoid arthritis, injury, and/or surgery to the knee) and had received physical therapy and/or intra-articular corticosteroid or hyaluronic acid injections during the last 6 months. Furthermore, patients were also excluded if they had history of cancer, dementia, neurological deficits, heart pacemaker, diabetes mellitus, uncontrolled hypertension, or morbid obesity (BMI≥40).

The study was approved by the Research Ethics Committee of King Saud Medical City, and all participants signed informed consent forms. The trial was registered in the Australian New Zealand Clinical Trials Registry, with the following number ACTRN12612000615886.

Sample size was estimated based on predictions of a 20 % improvement in the pain on VAS with standard deviation of 2. For a moderate-size effect, a sample of 34 for both groups would yield a power of approximately 0.8, at alpha level of 0.05 [25, 26]. Sample size was increased to 44 for possible drop out.

The patients were randomly assigned into active and placebo laser groups. Randomization was performed using sealed, randomly filled envelopes describing the treatment groups.

Clinical outcome measurements

All patients were evaluated and questioned about age, weight, height, duration of the knee OA and pain. In patients with whom both knees were symptomatic or when symptoms were similar bilaterally, both knees were chosen. The primary outcome measurement was the pain intensity on VAS. The secondary outcomes were knee function in terms of WOMAC subscales (pain, stiffness, and function) and the time required to walk distance of 50 ft. All outcome measurements were taken at baseline (W0) and post-intervention (W4).

Pain intensity using visual analog scale The VAS consists of the 10-cm horizontal line anchored by two extremes of pain: "no pain" at the left and "worst pain" at the right [27, 28]. The patients were provided with a translated Arabic version of VAS, with "no pain" on the right side and "worst pain" on the left side. Patients indicated their current level of pain intensity in their knee(s) and marked this with X on the 10-cm line. Then, the therapist measured the distance between the right side anchor "No pain" and the mark on the VAS by laying a transparent 10 cm ruler over the line. The pain intensity was recorded in centimeters. Pain intensity was recorded at rest and immediately following a 50-ft walking test.

WOMAC scores The WOMAC Index is a disease-specific, self-administered questionnaire. The WOMAC scale was used to measure pain (5 items), stiffness (2 items), and physical function (17 items). WOMAC scores were recorded on a five-point Likert scale of 0–4, where: 0 = no pain/limitation, 1 = mild pain/limitation, 2 = moderate pain/limitation, 3 = severe pain/limitation, and 4 = extreme pain/limitation. Maximum scores for pain, stiffness, and physical functions were 20, 8, and 68, respectively, with total scores 96 indicating greater disease severities. The WOMAC is a reliable and valid outcome measure for use in the evaluation

of patients with hip and knee OA [29, 30]. The Arabic Moroccan version of WOMAC is confirmed to be reliable and valid in patients with OA of the knee [31], while the Tunisia Arabic WOMAC questionnaire is reliable but not valid in its original form. Each subscale demonstrated good reliability and validity when compared with other versions [32].

Ambulation activity The time required to walk a distance of 50-ft "as fast as possible" was measured with stopwatch and recorded in seconds [33].

Intervention

All participants attended to the physical therapy department two times per week over a period of 4 weeks. Patients assumed a supine position lying on the treatment bed while the affected knee(s) was slightly flexed and supported with a pillow. During the therapy session, hot packs wrapped in toweling were placed on the target knee(s) for 20 min followed by laser therapy [34]. Patients in the active laser group received irradiation with a Ga–As laser device that had a wavelength of 850 nm, power of 100 mW, and spot size of 1.0 mm (Intellect Laser, Chattanooga, USA). Eight points were irradiated with LLLT; three on the medial side of the knee, three on the lateral side of the knee, and two on the medial edge of the tendon of the biceps femoris muscle and semitendinosus muscle in the popliteal fossa, as shown in Fig. 1. Each point received energy of 6 J/point for 60 s, with a total dose of 48 J/cm^2 in each session [13, 35]. All patients wore safety goggles. For patients in the placebo group, the treatment parameters were identical but without switching on the machine.

All patients were given home-based exercise program that consisted of isometric knee extension and straight leg raising exercise. These exercises were chosen because it could be continued by patients without difficulty at home. Each patient performed the exercise 10 times/set, for 3 sets with 2-min rest interval [35]. The patients maintained each contraction for 10 s with attention paid to feeling quadriceps muscle contraction and rested for 5 s. Photographic details of the home-based exercises were distributed to each patient with a dairy logbook. The patients were encouraged regarding compliance with the exercise, i.e., to record the number of days the exercises were performed per week. All patients were advised to keep their activity level and medication unchanged (paracetamol 2g daily) throughout the study period.

Statistical analyses

Statistical analyses were performed using SPSS software Statistical Package for the Social Sciences, version 18.0, SPSS Inc. Chicago, IL, USA). The qualitative variables were presented in terms of frequencies and percentage, and the quantitative variables were presented using mean and standard deviation. For analyses within the groups, the *t* test for paired data was used. Unpaired *t* test for parametric data and the Mann–Whitney test for nonparametric data were used for analyses between groups. The $p<0.05$ was considered significant.

Results

Demographic and baseline characteristics of the patients

Forty-four patients were eligible for the study, and four were excluded. Forty patients aged between 45 and 65 years participated in the study, and all of them completed the study period. Figure 2 represents the participants' flow chart.

Table 1 displays the demographic and baseline clinical characteristics of patients. Both groups were homogenous regarding age ($p=0.47$), BMI ($p=0.66$), duration of knee pain ($p=0.47$), and sex distribution ($p=0.75$). All patients had knee pain and reduced functional ability over the preceding 3 months. Radiographic examination showed knee OA of grade II (80 versus 85 %) and grade III (20 versus

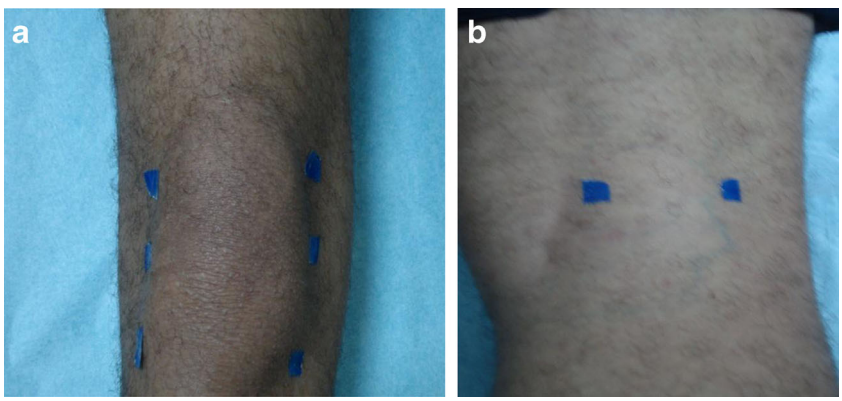
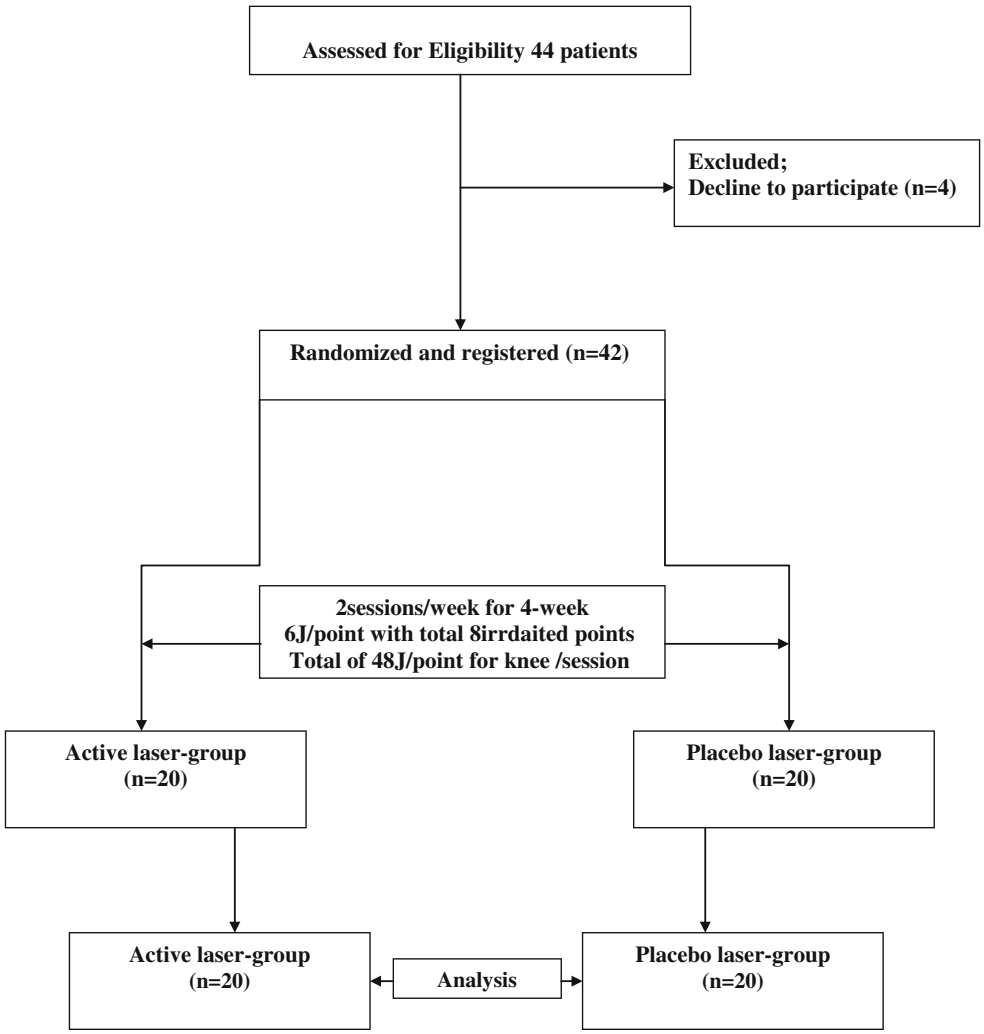


Fig. 1 Eight irradiated points with low-level laser. **a** Three points on lateral and medial aspect of knee; **b** two points on posterior aspect of the knee, medial to the tendon of the biceps femoris and semitendinosus muscles

Fig. 2 Participants' flow chart



15 %) for active and placebo laser groups, respectively. There were no significant differences in any of the assessment parameters at baseline ($p>0.05$) between both groups.

Pain intensity

Intergroup analysis showed statistically significant improvements in pain levels at rest, during movement, and post-intervention (W4) when compared to baseline (W0) ($p<0.05$). Between-groups comparison demonstrated significant reduction of pain intensity at rest ($p<0.05$) and during movement ($p<0.05$) as shown in Table 2. The mean percentages of reduction in pain intensity at rest and during movement were significantly greater in the active laser (47.26 and 40.39 %) compared to the placebo laser group (27.14 and20.15 %).

WOMAC scores

The values of WOMAC scores are shown in Table 2. Post-intervention (W4) WOMAC pain, stiffness, and function were significantly ($p<0.05$) improved within each group compared to baseline (W0). The differences in WOMAC scores for pain ($p=0.008$) and function ($p=0.001$) were significant, while no significant differences were observed in WOMAC scores for stiffness (0.08) between groups post-intervention (W4). The mean percentage of reduction in WOMAC pain (66.96 versus 41.67 %, p) and function (64.89 versus 40.7 %, p) were significant between active and placebo laser groups, respectively. There was no significant difference in the WOMAC stiffness post-intervention ($p=0.019$) between groups. However, the percentage reduction was greater for active laser (74.25 %) compared to placebo laser (58.74 %).

Ambulation activity

As observed in Table 2, there was significant reduction in walking duration post-intervention (W4) in both groups ($p<0.05$). The mean percentage of reduction in walking time was significantly higher in the laser group (14.59 %) when compared with placebo laser (7.6 %) post-intervention.

Table 1 Baseline demographic and clinical characteristics of patients

	Laser group (n=20)	Placebo group (n=20)	p value
Age (years)	55.2±8.14	57±7.77	0.47
BMI (kg/cm^2)	32.34±5.77	33.09±4.98	0.66
Gender			
Males	10 (50 %)	12 (60 %)	0.75
Females	10 (50 %)	8 (40 %)	
Duration of knee pain (months)	9.15±4.34	10.05±3.5	0.47
KL Radiographic grade			
Grade II	16 (80 %)	17 (85 %)	1
Grade III	4 (20 %)	3 (15 %)	
Side affected			
Right	2 (10 %)	5 (25 %)	0.34
Left	5 (25 %)	6 (30 %)	
Both	13 (65 %)	9 (45 %)	
Pain intensity			
Rest	5.6±1.27	6±1.16	0.3
Activity	7.45±1.05	7.55±1.35	0.79
Walking time	22±2.49	22.35±3.15	0.69
Activity-WOMAC			
Pain subscale	9.15±3.32	9.6±3.33	0.67
Stiffness subscale	2.8±1.76	3.45±2.21	0.31
Function subscale	25.95±9.23	30.7±11.03	0.14

No significant differences between groups (p>0.05)

BMI body mass index, *KL* Kellgren–Lawrence

Discussion

The results obtained from this study revealed that the application of low-level laser with energy of 6 J/point could be an important modality for treating symptomatic osteoarthritis. As active laser group had a significant improvement in respect to all variables such as pain, ambulation duration, and functional activities in comparison to the placebo group immediately after intervention.

The results of this study were supported by work of Fukuda et al., who found a significant improvement in pain and function in the laser group (energy density of 6 J/cm^2) compared with placebo at all assessment time [35]. Similar results were found in clinical work of Hegedus et al. [13] and Montes-Molina et al. [36]. They used an 830-nm laser with a dose of 6 J/point. Effective results were obtained regarding to pain relief in the irradiated area in the patients with knee OA.

The findings of this study are corroborated with Gur et al. [37], in which 90 patients were assigned into the following three groups: group I, with 3 J; group II, with 2 J; and placebo group. A significant improvement in pain, function, and quality of life were found among patients treated with laser therapy compared to placebo. Regarding the dose, the group that received 3 J showed a tendency to be better than the group that received 2 J, but without any statistical significance [36]. Moreover, an early study by Stelian et al., demonstrated significant functional improvement and pain reduction in the OA patients treated with 10.3 J red laser and 11.1 J infrared laser (treatment was applied on both sides of the knee, twice daily for 10 days) but not in the placebo group. Based on these findings, they concluded that LLLT is effective in pain relief and improvement of functional ability [38].

However, the results of this study are conflicting with many published trials. Recently, Hsieh et al. failed to demonstrated beneficial effects of LLLT, with 41.6 J/cm^2 per knee per session in either placebo or active laser groups with regards to pain and physical function [39]. Moreover, Tascioglu et al. did not find significant improvement in pain and activities assessed by WOMAC in patients receiving GA–Al–As laser of 830 nm and dose ranging from 1.5 to 3 J [40]. Similarly, Dominguez-Carrilho [41] failed to find significant effects of LLLT applied at 0.5 J/cm^2. Moreover,

Table 2 Pain, walking duration and functionality on WOMAC scales between both groups

Variables	Laser group (n=20)		Placebo group (n=20)	
	Mean±SD		Mean±SD	
	Baseline (W0)	Post-intervention (W4)	Baseline (W0)	Post-intervention (W4)
Pain intensity on VAS				
Rest	5.6±1.27	3.±1.25$^{\dagger *}$	6±1.16	4.4±1.27†
Activity	7.45±1.05	4.45±1.19$^{\dagger *}$	7.55±1.35	6.05±1.35†
Walking time (sec)	22±2.49	18.8±2.35$^{\dagger *}$	22.35±3.15	20.65±2.99†
Activity-WOMAC				
Pain subscale	9.15±3.32	3.25±2.61$^{\dagger *}$	9.6±3.33	5.5±2.5†
Stiffness subscale	2.8±1.76	0.95±1.23†	3.45±2.21	1.9±2.04†
Function subscale	25.95±9.23	10±7.39$^{\dagger *}$	30.7±11.03	18.2±9†

VAS Visual analog scale

*p<0.05 (Significant differences between groups); †p<0.05 (Significant differences within groups post-intervention)

early study by Bülow et al. [42] concluded that a laser of 830 nm with doses of 1.5 to 4.5 J, applied for 15 min with a total dose per treatment of 22.5 J, which was distributed as an average of 2.5 J per point failed to demonstrate significant improvement in patients with OA.

These contradictions in the literature may be attributed to variations in treatment parameters by LLLT, such as wavelength, power, energy density, number, and duration of treatment, size of exposure area, and method of laser administration. All of these will affect the clinical and therapeutic outcomes of laser applications. However, we find evidence that short-term LLLT improved pain, physical function, and activities in the patients with knee OA. Further studies are required to compare these different variables to confirm the results.

The exact mechanisms of laser action are still unclear. However, some data suggested that LLLT may produce analgesia by changing nerve transmission or by inhibiting sensory neural activity to raise the pain threshold. Laser irradiations also relieve pain by alleviating and removing swelling and by increasing oxygenation of the tissues, thus results in reduction of the pain. It has been postulated that LLLT might enhance joint cartilage regeneration achieved through the proliferation of chondrocyte synthesis and secretion of the extracellular matrix. Reed et al. observed macroscopic and microscopic smoothing of the fibrillated cartilage surface after laser irradiation in adult rabbits with mechanically induced degenerative knee arthritis [43]. Similarly, Bassleer et al. concluded that laser irradiation has cartilage stimulatory properties in humans [44], with increase proteoglycan synthesis after infrared laser irradiation [43]. On the other hand, Skinner reported that Ga–As laser had a significant stimulatory effects on fibroblasts function and enhanced connective tissue repair [45].

The major study limitations were the small sample size. So, further study of large sample size is necessary. Another limitation is the short-term follow-up; therefore, further studies should be conducted to evaluate the long-term effect of LLLT on pain relief and functional improvement.

Conclusion

In conclusion, LLLT seems to be an effective modality for short-term pain reduction and function improvement in patients with chronic knee OA

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Conflict of interest The authors have no conflict of interest to declare in this study.

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