

Research Paper: Effects of Low-Level Laser Versus Laser Acupuncture in Patients With Knee Osteoarthritis: A Randomized Controlled Trial



Ali Lafta Mezaal¹, Siamak Bashardoust Tajali^{1*}, Gholamreza Olyaei¹, Shohreh Jalaie¹, Saddi Thweab Alwatifi²

1. Department of Physiotherapy, School of Rehabilitation, Tehran University of Medical Sciences, Tehran, Iran.

2. Higher Diploma of Rheumatology Rehabilitation, Al-Suwaira Hospital, Wasit, Iraq.



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ABSTRACT

Introduction: Osteoarthritis (OA) is one of the common causes of disabilities in adults. The prevalence of Knee Osteoarthritis (KOA) is approximately 4.9% among people over 26, 16.7% among people over 45, and 12.1% among people over 60 years old. This study aims to determine the effects of Low-Level Laser Therapy (LLLT) and laser acupuncture in decreasing pain and increasing functional activity in patients with subacute and chronic KOA.

Materials and Methods: In this randomized, single-blind, controlled study, the patients with grades 2 and 3 primary KOA were assigned into two experimental groups (active low-level laser and acupuncture laser) and one control group (infrared & exercise). The patients in the experimental group I (n=23) were under low-level Ga-Al-As diode laser, 830-nm continuous waves, and received laser irradiation of 30 mW/cm² power density, 3 mW output power, 0.1 cm² spot size, with a total dose of 18 J and for 10 minutes on 6 acupuncture points (SP10, ST34, ST35, GB34, Xiyan, SP9) around the knee in each session. The patients in the experimental group II (n=23) received 3 J power irradiation in each cm² in a gridding technique over a triangle-like surface of 15 cm² over the medial, lateral, and anterior sides of the knee with a total energy density of 45 J/15 cm² for each session. Laser therapy was applied 5 times per week for a period of two weeks (10 sessions in total). The patients in the control group (group III) were under conventional physiotherapy (superficial heat therapy and isometric knee exercises for 15 minutes every day for a similar period (10 sessions in 2 weeks). The outcome study measures were pain level at rest rated by Numeric Rating Scale (NRS), Western Ontario and McMaster Universities Osteoarthritis index (WOMAC), and Short Form of McGill Pain Questionnaire (SF-MPQ). In addition, active knee flexion and extension Range of Motions (ROMs) were measured too. These variables were evaluated at the baseline time, before the intervention, and after the intervention, on the final day of the intervention.

Results: Based on statistical outcomes, a significant pain reduction by NRS and McGill, an increase in functional activity by WOMAC as well as an increase in the Range of Motion of the knee were observed in three study groups after 10 sessions. However, the result of ANOVA test showed significant difference in pain reduction among three groups and the post hoc Least Significant Difference (LSD) test showed the significant difference between laser acupuncture and conventional laser groups with the control group; the largest improvement was found in Group I. In terms of functional activity, the post hoc LSD test showed the significant difference between conventional laser and laser acupuncture groups with the control group; the largest improvement was found in Group II. No significant difference was observed among the three groups with regard to the mean values of active knee flexion and extension.

Conclusion: Laser acupuncture and conventional laser are more effective in reducing pain and increasing functional activity in patients with KOA compared to conventional treatment. Clinically, laser acupuncture would appear to be superior in pain reduction.

Keywords:

Low-Level Laser, Laser acupuncture, Knee, Osteoarthritis

* Corresponding Author:

Siamak Bashardoust Tajali, PT, PhD.

Address: Department of Physiotherapy, School of Rehabilitation, Tehran University of Medical Sciences, Tehran, Iran.

Tel: +98 (21) 77685105

E-mail: s_bashardoust@sina.tums.ac.ir

1. Introduction

Osteoarthritis (OA) is a degenerative disease characterized by progressive loss of articular cartilage combined with subchondral sclerosis, joint space narrowing, marginal osteophytes, subchondral cysts, and finally joint deformation. Osteoarthritis may clinically present by pain, restricted Range of Motion, and muscle weakness [1]. These problems can cause difficulties in daily living activities and impaired quality of life [2, 3]. Based on data collected from several large population-based studies, it is estimated that approximately 12% of the western countries' population or 27 million adults aged 25 or older have clinical OA of some joints [4]. It is the most common form of arthritis and extremely prevalent among individuals older than 40 years [5].

The age-related changes in muscle strength and Knee OA (KOA) increase susceptibility to falls, which are associated with significant morbidity and mortality in the elderly [6]. No definite factor that predisposes an individual to OA has yet been identified, but aging is strongly associated with OA [7]. Genetic factors account for 39% to 65% of radiographic OA of the hand, hip, and knee in women and as much as 70% of OA cases of the spine [8]. Repetitive microtrauma in the etiology of OA has also been mentioned [7]. Finally, obesity has been shown to be a risk factor for the development of OA in old age, most evident in the knee joint and to a lesser extent in the hip and hands [9].

Medical therapies generally focus on pain and inflammation reduction. Early aggressive pharmacological therapy is associated with prevention of joint damage and preservation of long-term function. The major classifications of drugs used in Rheumatoid Arthritis (RA) management include Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) and Disease-Modifying Antirheumatic Drugs (DMARDs), which include the Biological Response Modifiers (BRMs) and corticosteroids. However, 2% to 4% of the patients experience serious adverse effects, including gastrointestinal bleeding, ulcers, and perforation [10]. Subsequently, nonpharmacological treatments must be prioritized as first-line therapy, especially in older adults. Some non-pharmacological methods are exercise [11], heat [12], cold [13], ultrasonic therapy [14], electromagnetic therapy [15], transcutaneous electrical nerve stimulation [16], orthoses [17], patellar taping [18], acupuncture [19], patients' education [20], and Low-Level Laser Therapy (LLLT) [21].

LLLT has the potential physiologic and therapeutic effects for the OA care, since absorption of light energy by the chromophores (i.e. mitochondrial cytochromes) is presumed to trigger the photobiomodulation effects such as analgesia, anti-inflammation, and increase in protein and collagen synthesis, which enhance cellular metabolism and promote function and soft-tissue healing [22]. The effect of the LLLT on the KOA is related to the number of affected points, laser wavelength, energy density, continuous or pulse mode application, treatment duration, the method of application, number of sessions, follow-up, the severity of the OA, and surface of application [23].

The effects of these factors should be investigated on the LLLT effectiveness for the OA in randomized controlled clinical trials [24]. The previous randomized controlled trial just used Visual Analog Scale (VAS) for assessing pain and their results were very different [25].

Tascioglu et al. [26] used Gal-Al-As diode laser device with 830 nm wavelength, two treatment groups with dosage 3J per point and 1.5 J per point, respectively. The laser therapy was done 5 times per week with 10 sessions in total. They suggested that LLLT has no effect on pain in patients with KOA. There were no significant differences between the two groups based on performance improvement, pain relief, and other clinical outcomes [26, 27]. Results of Huang and colleagues [28] meta-analysis on 612 studies and 9 RCTs with a total 518 patients show that the Standardized Mean Difference (SMD) in Visual Analog Scale (VAS) pain score Right After the Therapy (RAT) and then 2 weeks after the therapy was not significantly different between LLLT and control (SMD=-0.28 [95% CI=-0.66, 0.10], I²=66%).

There were no substantial differences regarding VAS pain score following low-level laser application in patients with Osteoarthritis during a period of 12 weeks follow-up. Similarly, there was no evidence of LLLT effectiveness based on Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain, stiffness or function outcomes (5 and 3 studies had outcome data right after therapy and 12 weeks after therapy, respectively). But Rayegani and colleagues [23] analysis reports a significant pain reduction in patients who received the LLLT. The efficacy of the LLLT in the KOA patients has remained unknown due to these conflicting results.

Different types of electrophysical appliances are applied to trigger the acupuncture points to relieve pain. One of these tools is low-level lasers [29, 30]. A different

technique in the acupuncture field is the laser acupuncture which is a non-intensive technique. Yet it is more than just the summation of two different forms of therapy. What makes laser acupuncture so interesting is the synergy that exponentially increases the effects of both acupuncture and phototherapy [31]. There are several review articles concerning clinical effectiveness of laser acupuncture [31]. However, few published studies have investigated the efficacy of laser acupuncture on KOA and their reports are contradictory [32-36].

The rationale of this study is to compare the effects of LLLT with two other methods of application (gridding technique and laser acupuncture technique) and measuring the multiple dimensions of acute and chronic pain. The McGill Pain Questionnaire (MPQ) is a reliable and valid generic pain measurement tool. It is a perfect tool for the research purposes to describe quantity (intensity) and quality of pain in patients with Knee Osteoarthritis [25].

2. Materials and Methods

This study was designed as a single-blind randomized clinical trial and conducted at the Department of Rehabilitation in Al-Suwaira Hospital, Wasit Governorate, Iraq between April 2018 and December 2018. All the procedures were carried out after the study was approved by the Scientific Board and Ethics Committee of the School of Rehabilitation, Tehran University of Medical Science (IR.TUMS.FNM.REC1397.161). All participants were informed about the procedures that would be carried out. The participants who agreed voluntarily to sign an identified consent form were considered for the study.

Study patients

The patients from both genders aged between 35 and 70 years with a Mean±SD age of 56.65±8.568 years were recruited for the study. They were randomly assigned into three groups; laser acupuncture (n=23), conventional laser (n=23), and conventional physiotherapy (n=23). The participants who met the inclusion criteria were enrolled in this study, including: 1. Grade II or III of KOA according to the Kellgren and Lawrence grading system [37]; 2. Minimum score of 25 or more based on the Western Ontario McMaster Universities Osteoarthritis index (WOMAC); 3. Knee pain score equal to 4 or more for the last month based on the Numeric Pain Rating Scale (NPRS); and 4. The ability to participate in the study and follow the treatment schedule. The exclusion criteria were having the history of any knee op-

eration, history of any hormonal, metabolic, systemic, or rheumatologic problems leading to secondary KOA, history of using oral analgesic or NSAIDs in the previous 4 weeks. Moreover, patients would also be excluded from the study if they had a history of malignancy, mental retardation, neurologic dysfunction, having a heart pacemaker, diabetes mellitus, uncontrolled hypertension, or morbid obesity (BMI≥40).

The patients were randomly assigned into laser acupuncture group, conventional laser group, and conventional physiotherapy group. Simple random sampling was performed using sealed, randomly filled envelopes describing the treatment groups. The patients did not have any idea that they were in a conventional laser group or laser acupuncture group since the laser device was similar in both groups. Besides, the statistical analyzer did not have any idea about the type of intervention provided for each group. Based on previous studies, a significant difference improvement in the NPRS was defined as 4.71 cm [38], at the alpha level of 0.05 and power of 0.8 resulted in an estimated sample size of 23 [39], so a total of 69 patients were recruited for the three study groups.

Study intervention

The study was conducted for 2 weeks in 10 sessions, 5 sessions per week. The participants were assessed before the treatment (at the baseline) and after the treatment. The assessor asked the patients to lie in the supine position and flex the affected knee 20° supporting with some pillows. Treatments were performed at the same location and under similar conditions for both laser groups using similar laser device (low-level gallium-aluminum-arsenide laser of 810 nm, Lasermed 4098 Carci, Brazil). In group I, each patient received acupuncture LLLT with a dosage of 3 J on all six points around the knee. These points were identified from the reference acupuncture book (six points were around the knee joint medially and laterally, including SP10, ST34, ST35, GB34, Xiyuan, SP9) [40].

All these points are outside of the area that will be treated by the gridding technique. Laser therapy would be provided 5 times per week for a period of 2 weeks. The output power of laser producer was 30 mW and laser irradiation was applied in a continuous mode of 830 nm wavelength. Each point received energy of 3 J per point for 100 s, with a total dosage of 18 J in each session. In group II, each patient received gridding technique LLLT over 15 cm² triangle-like on the medial, lateral, and anterior knee gap and each cm² received 3 J for

100 s, for a total dosage of 45 J/15 cm². In group III, the patients received heat therapy (infrared lamp of 150 W) for 15 minutes and isometric knee isometric exercises (quadriceps setting exercise).

In the isometric quadriceps exercise, the patients lay in a supine position. A rolled-up towel was put beneath the knee and isometric exercise was performed 10 times per set for three sets with 2-min rest between each set. The patients maintained each contraction for 10 s focusing on the quadriceps muscle contraction [41]. All participants and practitioner wore safety goggles during the procedure.

Clinical outcome measurements

The same practitioner gave instructions to the patients for the questionnaires and performed outcome measures and collected initial data, including age, weight, height, duration of knee OA and level of pain. If the patients demonstrated symptoms on both knees or when symptoms were similar bilaterally, the dominant painful knee was chosen. The primary outcome measurement was the pain intensity by NPRS and McGill Pain Questionnaire, while WOMAC was used for measuring functional activity with its subscales (pain, stiffness, and function). All outcome measurements were taken at baseline and after the intervention (2 weeks).

Pain assessment

Numeric Pain Rating Scale (NPRS) is an 11-point numeric scale ranges from 0 representing no pain to 10 representing the extreme pain [25] (Appendix 1). The patients were tested with a translated Arabic version of NPR scale, with “no pain” on the left side and “worst pain” on the right side of the line. The patients pinpointed their current level of pain intensity in the knee and marked this with a symbol like X on the 11-point line. Then, the practitioner registers this number.

Short-form McGill Pain Questionnaire (SF-MPQ) is a shorter version of the original MPQ, and was prepared in 1987 [42] (Appendix 2). The SF-MPQ rating index has 2 subscales 1. Sensory with 11 words; and 2. Affective with 4 words extracting from original MPQ. These words or items are rated on an intensity scale from 0 to 3 demonstrating none, mild, moderate and severe levels of pain, respectively. There is also one item for present pain intensity and one item for 10 points numeric rating for average pain. In this study, the Arabic version of SF-MPQ was used because the respondents were Arabs [42].

Functional activity assessment

Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) [43] questions are scored on a basis of 4-point scale, demonstrating from none (0) to mild (1), moderate (2), severe (3), and extreme (4) (Appendix 3). The scores of each subscale are summed up with possible scores of pain from 0 to 20, stiffness from 0 to 8, and physical function from 0 to 68. The sum of all three subscales is commonly considered as a total WOMAC score. The Arabic version of WOMAC is approved to be reliable and valid in patients with KOA [44].

Active knee Range of Motion

Active extension knee Range of Motion was measured with electronic stainless-steel digital angle ruler (Wenzhou Sanhe Measuring Instrument Co., Ltd. China Mainland Zhejiang). It is a valid and reliable measurement tool. In maximal knee extension measurement, the patient is positioned supine with the hip of the tested leg in 90 degrees of flexion. The contralateral leg stays flat on the examination table. The patient extends the knee and tries to reach a maximally tolerable stretch of hamstring muscle as indicated by the practitioner, while the ipsilateral hip remains in 90 degrees of flexion. The knee angle is then measured. The axis of the ruler should be placed at the lateral epicondyle of the femur. The moving arm should point towards the lateral malleolus and the stationary arm towards the greater trochanter [45].

Active flexion knee Range of Motion was measured with electronic stainless-steel digital angle ruler. It is a valid and reliable measurement tool. It was evaluated in a prone lying position, with the extended knee. The patient was asked to bring the heel of the tested leg as close as possible to the buttock while the other foot remained in contact with the plinth. The fulcrum of the goniometry is placed on the lateral epicondyle of the femur of the tested knee with one arm in line with the lateral malleolus and the other arm in line with the greater trochanter [45].

Statistical analysis

The collected data were statistically analyzed in SPSS (version 20.0). After checking the assumptions, the paired t-test was used to determine the significant improvements within each group. Analysis of Variance (ANOVA) was used to detect the significant differences among the three groups after physical therapy interventions. The Least Significant Difference (LSD) test was used to determine any group that had the best significant

improvements. The Independent t test was used to determine the difference among groups based on the KOA grades (Kellgren and Lawrence grade scale) for improvements. The correlation test was used to find any correlation between the improvements. $P < 0.05$ was considered statistically significant at 95% confidence interval.

3. Results

A total number of 69 patients (21 [30.4%] men and 48 [69.6%] women) completed this study. Their Mean±SD age was 55.12±8.357 years. All patients had KOA; 45 (65.2%) in the right and 24 (34.8%) in left knee. Forty-four (63.8%) patients had grade II and 25 (36.2%) patients had grade III of KOA. The baseline demographic and clinical characteristics of patients in the three groups

were similar with no statistically significant differences (Table 1).

Pain intensity

McGill Pain Questionnaire

According to Table 2, after applying the intervention in patients with KOA, significant differences were observed between all scores of McGill parameters ($P < 0.05$).

Numeric Pain Rating Scale

As Table 3 indicates, the numeric pain rating scale showed a statistically significant improvement for all study groups after 10 sessions of treatment ($P \leq 0.001$). Just one case in group three showed no improvement.

Table 1. Baseline characteristics of study groups

Characteristics		Laser Acupuncture Group (n=23)	Conventional Laser Group (n=23)	Conventional Physiotherapy Group (n=23)
Age (y)	Mean±SD	56.65±8.568	57.30±6.852	51.39±8.574
Gender (n)	Male	5	6	10
	Female	18	17	13
Body Mass Index (kg/m ²)	Mean±SD	30.81±4.934	28.66±4.111	29.43±3.445
The degree of Knee Osteoarthritis	Grade II	13	16	15
	Grade III	10	7	8
WOMAC Osteoarthritis Index	Mean±SD	49.35±12.375	50.30±13.858	42.52±11.413
McGill Pain Questionnaire	Mean±SD	32.3478±7.15801	31.5652±7.91906	32.9130±7.93103
Numeric Pain Rating Scale	Mean±SD	7.1304±1.39167	7.2174±1.38027	6.7609±0.92772
Active Knee flexion (degree)	Mean±SD	110±10.57871	115.6±7.63210	111±11.45139
Active Knee extension (degree)	Mean±SD	-2.48±3.217	-1.70±1.917	-2.09±2.314

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Table 2. Results and statistical comparisons of the pre-treatment and post-treatment (second weeks) scores of McGill questionnaire in groups I, II, and III

Before Treatment	After Treatment		95%CI of the Difference	P	
	Mean±SD	Mean±SD			
McGill	G1	32.3478±7.15801	12.2174±4.89858	(23.93241) to (16.32846)	<0.001
	G2	31.5652±7.91906	12.0000±3.43776	(22.06241) to (17.06802)	<0.001
	G3	32.9130±7.93103	30.4348±7.48226	(1.99269) to (2.96383)	<0.001

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Table 3. Results and statistical comparisons of the pre-treatment, post-treatment (2 weeks) scores of numeric pain rating scale in groups I, I, and III

Group		Median	Ranks	Z	P
GI	Before	7.00	Positive 23	-4.258	<0.001
			Negative 00		
	After	3.00	Ties 00		
GII	Before	7.00	Positive 23	-4.272	<0.001
			Negative 00		
	After	4.00	Ties 00		
GIII	Before	7.00	Positive 22	-4.203	<0.001
			Negative 00		
	After	5.00	Ties 1		

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WOMAC Osteoarthritis Index

Based on Table 4, the WOMAC Osteoarthritis Index showed a statistically significant improvement for the laser acupuncture group after 10 sessions of treatment ($P < 0.05$). Also, the mean rank test results of all cases in conventional laser show that it had positive effects ($P < 0.001$). In the third group, the results showed a statistically significant improvement after 10 sessions of treatment ($P = 0.00$), except for two cases.

Active flexion Range of Motion

Table 5 Wilcoxon signed-ranks test results indicate a significant improvement ($P = 0.003$). The ranks show that 11 cases in the acupuncture laser group had positive results in active flexion ROM for knee and 12 cases had no change. According to Table 6, significant differences are observed after the treatment in the second group ($P = 0.008$), and the third group (conventional physiotherapy) ($P = 0.006$).

Table 4. Results and statistical comparisons of the pre-treatment, post-treatment (second week) WOMAC Osteoarthritis Index in groups I, II, and III

Group		Median	Ranks	Z	P
G I	After	19.00	Positive 23	-4.198	<0.001
			Negative 00		
	Before	53.00	Ties 00		
G II	After	13.00	Positive 23	-4.199	<0.001
			Negative 00		
	Before	52.00	Ties 00		
G III	After	37	Positive 21	-4.072	<0.001
			Negative 00		
	Before	40	Ties 2		

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Table 5. Results and statistical comparisons of the pre-treatment, post-treatment (second week) of active flexion Range of Motion in group I

Assessment	Median	Ranks	Mean Rank	Z	P	
GI	Pre-treatment	110	Positive	11	6	-2.966 0.003
			Negative	0	0	
	Post-treatment	115	Ties	12		

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Table 6. Results and statistical comparisons of the pre-treatment, post-treatment (second week) of active flexion Range of Motion in groups II and III

Group	Before Treatment	After Treatment		
	Mean±SD	Mean±SD	95% CI of the Difference	P
GII	115.6087±7.63210	119.0000±6.22312	5.79453 - 0.98808	0.008
GIII	111.0435±11.45139	112.3913±11.44449	2.25686 - 0.43879	0.006

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Active extension Range of Motion

The result of Table 7 shows that acupuncture laser group has significant effectiveness (P=0.024), in group of acupuncture laser it has significant effectiveness (P=0.024) and conventional physiotherapy group it has significant effects in active flexion ROM for knee (P=0.016), 12 cases without any change and 1 case with negative effectiveness.

Table 8 shows the improvement in all parameters of the studied groups. The results show a significant difference in WOMAC, McGill, and NPR scale. With regard to WOMAC improvement, the post hoc test by using adjusted P in Mann-Whitney shows that the significant difference is related to the groups of laser acupuncture with conventional physiotherapy and conventional laser with conventional physiotherapy therapy (P=0.000). With regard to McGill improvement, the post hoc test by using adjusted P in Mann-Whitney shows that the significant difference is related to the groups of laser acupuncture

Table 7. Results and statistical comparisons of the pre-treatment, post-treatment (second week) of active extension Range of Motion in groups I, II, and III

Groups	Median	Ranks	Z	P	
GI	Before	0.00	Positive	6	-2.226 0.026
			Negative	0	
	After	0.00	Ties	17	
GII	Before	0.00	Positive	6	-2.264 0.024
			Negative	0	
	After	0.00	Ties	17	
GIII	Before	0.00	Positive	10	-2.404 0.016
			Negative	1	
	After	-2.00	Ties	12	

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Table 8. Comparison for improvement in mean and median parameters for studied groups with Kruskal-Wallis H test

Outcome Measurement	Mean±SD			χ ²	P
	Group I	Group II	Group III		
WOMAC improvement	29.78±13.79	32.39±12.8	2.6087±1.19	45.707	<0.001
McGill improvement	20.13±8.79	19.56±5.77	2.4783±1.12	45.532	<0.001
NPRS improvement	3.95±1.364	3.82±1.26	1.7391±0.76	35.935	<0.001
Flexion improvement	3.737±2.82	5.55±3.39	2.10±1.3478	1.594	0.451
Extension improvement	1.475±0.7826	1.38±0.7826	1.21±0.7391	0.342	0.843

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with conventional physiotherapy and conventional laser with conventional physiotherapy (P≤0.001).

With regard to NPRS improvement, the post hoc test by using adjusted P in Mann-Whitney shows that the significant difference is related to the groups of laser acupuncture with conventional physiotherapy and conventional laser with conventional physiotherapy (P≤0.001). Kruskal-Wallis H test showed a non-significant difference in mean values of active knee flexion and extension improvement among the three groups (P>0.05) (Figure 1).

4. Discussion

Osteoarthritis (OA) of the knee joint is a major cause of pain and locomotor disability all over the world. This is the first clinical study to compare the effects of Low-Level Laser Therapy versus laser acupuncture in patients with Knee Osteoarthritis. Based on our study results, the application of Low-Level Laser Therapy (LLLT) or laser acupuncture has a beneficial effect on reducing pain intensity and improving functional outcome in patients

with KOA compared to the conventional physiotherapy. However, we did not find any significant differences in the Range of Motion between laser groups and conventional physiotherapy group.

The dose of 3 J that was used in this study was recommended by WALT for KOA [26]. The intervention was performed in five sessions per week for 2 weeks. Our study showed a statistically significant difference in WOMAC improvement between the LLLT and the control group (P≤0.001) also between the laser acupuncture and the control group (P≤0.001). Regarding the pain intensity, McGill and NRP scale showed improvement in the LLLT group compared with the control group (P≤0.001) also between the laser acupuncture group and the control group (P≤0.001).

However, the results of this clinical study are inconsistent with many published clinical trials. Recently, Tascioglu et al. [47] reported that LLLT has no effect on pain in patients with KOA by the dose of 3 J. This failure in pain reduction may be due to the laser modality, dosages, site of points, and wavelength selection used in this trial. Yurtkuran et al. [35] conducted a clinical trial to inves-

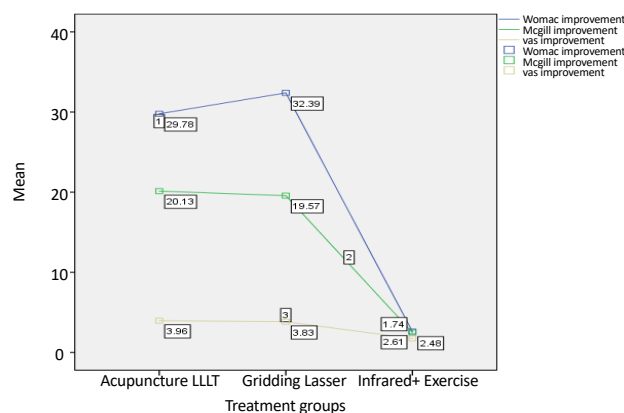


Figure 1. Levels of improvement for all outcome measures among the experimental groups

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tigate the effects of laser acupuncture in knee OA and compared it with placebo treatment. The acupuncture point of Sp9 was irradiated for 120 s (0.48 J) treatment time per session.

The result showed an improvement of knee swelling as shown by better knee circumference measurement in the laser group compared to the placebo group. The results of our study are different from the study conducted by Yurtkuran et al. The variation may be due to lower laser doses. They used a dose that may be too low, in addition, they used just one acupuncture point. Yurtkuran et al. used a laser device with a power density of 10 mW/. This power density may be very low to affect mast cell degranulation, which is important to stimulate the acupuncture point [47].

An early study by Bülow et al. [27] concluded that laser irradiation, with 830 nm wavelength and dosages of 1.5 to 4.5 J, applied for 15 minutes with a total dosage of 22.5 J per session (distributed as an average of 2.5 J per point) failed to demonstrate substantial improvement in patients with the OA. This opposite result might be related to inappropriate dosages (very low) that were applied per point plus the unsuitable site of points that might not be appropriate for the treatment. These discrepancies may be attributed to variations in parameters of LLLT such as wavelength, number of points, power, energy density, the method of laser administration, duration of treatment, size of the exposure area, and method of laser administration.

All of these factors will affect the clinical and therapeutic outcomes of laser applications. However, our study results suggest that short-term LLLT improves pain, physical function, and activities in patients with KOA. Further studies may be required to investigate the effect of these different variables to confirm the difference in results. Al Rashoud et al. [34] conducted a clinical trial to evaluate the efficacy of LLLT on acupuncture points of knee joint combined with exercise. These researchers applied lower dosage and power density. Their results demonstrated that short-term application of the LLLT on specific acupuncture points along with exercises was effective to reduce pain and improve quality of life in patients with KOA [34].

The results of this study are similar to the result of Fukuda et al. who found a significant improvement in pain and function in the laser group (energy of 3.0 J per point) compared with placebo in all the assessments applied to the groups [48]. Similar results were found in clinical trials of Rayegani et al. [49] and Hegedus et al. [50]. They

used Ga-Al-As laser with a dose of 6 J per point. The results show that LLLT reduces pain, joint stiffness, and disability in KOA.

The findings of this study agree with the results of Dwi R. Helianthi et al. [33] study that compared the effectiveness of active laser acupuncture with placebo in reducing pain intensity and improving functional outcome in older patients with KOA. A total of 62 patients with knee OA were treated by using a gallium aluminum arsenide laser device at 5 acupuncture points over the affected knee for 10 sessions. The researchers found that the active laser acupuncture is effective in reducing pain and improving functional ability.

The exact physiologic and therapeutic effects of LLLT on human soft tissues are, unfortunately, far from well-established or understood. There is a strong consensus in the scientific literature, however, that LLLT induces photobiomodulation effects through photochemical interactions between photons and healthy cells within and around the soft-tissue pathology [51].

Former research studies revealed that the LLLT application had a wide range of effects at molecular, cellular, and tissue levels. Besides, the specific modes of action may lead to various effects on different applications [51]. The strong evidence suggests that the LLLT affects mitochondria action [52], increases Adenosine Triphosphate (ATP) production [53], modulates Reactive Oxygen Species (ROS), and induces transcription factors within cell level [54].

Several transcription factors are regulated by changes in cellular redox state such as redox factor-1, dependent activator protein-1 (a heterodimer of c-Fos and c-Jun), nuclear factor kappa B, p53, activating transcription factor/cAMP-response element-binding protein, Hypoxia-Inducible Factor (HIF)-1, and HIF-like factor [54]. These transcription factors improve protein synthesis and trigger further effects, such as increased cell proliferation and migration (particularly in fibroblasts), modulation of cytokines, growth factors and inflammatory mediators, and increased tissue oxygenation [55].

Serra et al. [56] suggested that analgesic effects of laser acupuncture came from low-level laser effects to increase the peripheral release of opioids through migration of immune system cells, with local release of beta-endorphin, which is antagonized by naloxone. When the histamine concentration increases, the nociceptors again become depolarized and rhythmic discharges may initiate. This may be the basic mechanism of laser acupuncture.

ture and suggests the important role of connective tissue in acupuncture.

Laser acupuncture and conventional laser have the same effect on reducing pain and increasing functional activity in patients with KOA and they are more effective when compared to the conventional treatment. Longer follow-up period is still necessary for further evaluation of the efficacy of the treatment modality.

Ethical Considerations

Compliance with ethical guidelines

All the procedures were carried out after the study was approved by the Scientific Board and Ethics Committee of the School of Rehabilitation, Tehran University of Medical Science (IR.TUMS.FNM.REC1397.161). All participants were informed about the procedures that would be carried out. The participants who agreed voluntarily to sign an identified consent form were considered for the study.

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Authors' contributions

Carrying out the literature search and review, data extracting, synthesizing results, preparing the initial draft, performing the statistical analysis, and submitting the manuscript: Ali Lafta Mezaal; Literature search and review, preparing the research framework, coordinating appraisal, Data critical appraisal, and preparing the manuscript revisions: Siamak Bashardoust Tajali; Search strategy and revisions of the manuscript: Gholamreza Olyaei, Shohreh Jalaie, Saddi Thweab Alwatifi; Statistical suggestions and analysis: Shohreh Jalaie; and Reading and approving the final article: All authors.

Conflict of interest

The authors declared no conflict of interest.

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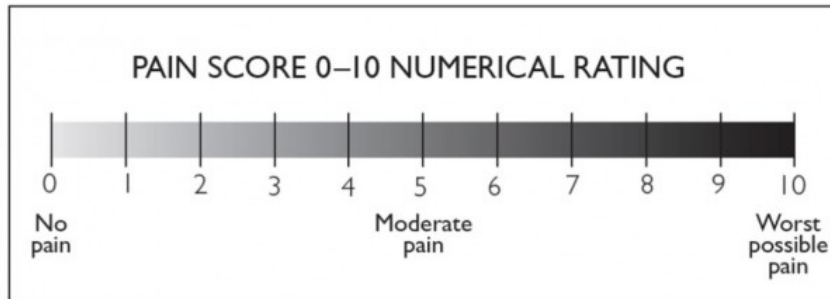
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Appendices

1. Numeric Rating Scale pain



2. Short Form of McGill Pain Questionnaire (Arabic version)

Short-Form McGill Pain Questionnaire (SF-MPQ)

عزيزي المريض:

بما أنك قد ذكرت لنا أن أحد الأعراض والمشاكل المصاحبة لك هو الألم الجسدي، فإن الغرض من هذه الإستمبيان هو تقييم شعورك بهذا الألم. علماً أن كلاً من الكلمات في العمود الأيمن يصف نوعية وميزة الألم لديك. ولذلك، يرجى تقييم نوع الألم الذي تشعر به بوضع علامة (✓) أمام كل نوع في العمود الأيمن وعلى حسب شدة الألم، حيث أن (0) تعني لا يوجد، (1) خفيف، (2) متوسط، (3) شديد.

الرجاء وضع علامة (✓) في المكان المناسب:

شديد (3)	متوسط (2)	خفيف (1)	(0) لا يوجد	نوع الألم
				1- أشعر بالألم كالتنبيه (خافق)
				2- أشعر بالألم ضارب
				3- أشعر بالألم كالطعنات
				4- أشعر بالألم حاد
				5- أشعر بالألم كالتقلصات
				6- أشعر بالألم قارض (قضم)
				7- أشعر بالألم حارق
				8- أشعر بالألم ثابت موجع
				9- أشعر بالألم الإحساس بالنقل
				10- أشعر بالألم عند الضغط أو اللمس
				11- أشعر بالألم كالتمزق (تقطع)
				12- الألم مُتعب و مرهق
				13- الألم مُمرض (مقزز)
				14- الألم مقلق (مخيف)
				15- أشعر بالألم قاسي - شديد

الرجاء قم بوضع دائرة حول الرقم الذي يعكس شدة الألم لديك:

لا يوجد ألم 0 1 2 3 4 5 6 7 8 9 10 أسوأ ألم ممكن

الرجاء اختيار أفضل خيار يصف الألم الذي تشعر به:

1. لا يوجد ألم

2. ألم خفيف

3. ألم مزعج

4. ألم مقلق

5. ألم فظيع

6. ألم مبرح معذب جداً

هل الألم الذي تشعر به في الوقت الحالي؟

يأتي على فترات قصيرة متقطع متواصل

(اختر اجابة واحدة):

From: Ronald Melzack, The short-form McGill Pain Questionnaire. Pain, 30 (1987) 191 – 197.

3. The Western Ontario and McMaster Universities Arthritis Index (WOMAC) (Arabic version)

WOMAC index

استمارة وماك

- 0 : not any
1 : a little
2 : moderate
3 : important
4 : very important - extreme

- 0 - لا شيء
1 - قليلة،
2 - متوسطة،
3 - كبيرة
4 - كبيرة جدا.

P Subscale :**أ) الأوجاع :**

How much pain do you have:

ما هي شدة الأوجاع التي تحس بها ؟

- 1: walking on flat surface
2: going up or down stairs
3: at night while in bed
4: sitting or lying
5: standing upright

- 1 - عندما تمشي على أرض مستوية.
2 - عندما تصعد أو تنزل الدرج.
3 - في الليل و أنت في فراشك.
4 - عند الجلوس أو الاستلقاء.
5 - عند الوقوف.

S Subscale :

how severe is your stiffness

ب) اليبوسة أو التصلب المفصلي :
ما هي شدة اليبوسة بمفاصلك ؟

- 1: After first wakening in the morning
2: After sitting lying or resting later in the day

- 1 - عندما تستيقظ في الصباح.
2 - بعد الجلوس أو الاستلقاء أو الاستراحة أثناء النهار.

PF subscale:**ج) الحركة الوظيفية :**

What degree of difficulty do you have

ما هي شدة الصعوبة ؟

- 1: descending stairs
2: ascending stairs
3: rising from sitting
4: standing
5: bending to floor
6: walking on flat
7: getting in / out of car
8: going shopping
9: putting on socks / stockings
10: rising from bed
11: taking off socks / stockings
12: lying in bed
13: getting in / off bath
14: sitting
15: getting on / off toilet
16: heavy domestic duties
17: light domestic duties

- 1 - عندما تنزل الدرج.
2 - عندما تصعد الدرج.
3 - عند الوقوف بعد الجلوس
4 - عند الوقوف.
5 - عندما تتحني إلى الأرض.
6 - عندما تمشي على أرض مستوية.
7 - عندما تركب أو تنزل السيارة.
8 - عندما تذهب إلى السوق.
9 - عندما تلبس الجوارب (القلميط، الكاسط، النقاش)
10 - عندما تقوم من الفراش.
11 - عندما تنزع الجوارب (القلميط، الكاسط، النقاش)
12 - عندما تستلقي على الفراش.
13 - عندما تدخل أو تخرج من حوض الاستحمام.
14 - عند الجلوس على الكرسي.
15 - عندما تجلس أو تقوم من المراض.
16 - عندما تقوم بأعمال منزلية كبيرة.
17 - عندما تقوم بأعمال منزلية خفيفة.