

Effects of Class IV Laser in Knee Osteoarthritis: A Randomized Control Trial

Bettencourt F*

Department of Medicine, Sporting Clube de Portugal, ComCorpus Clinic, Lisbon, Portugal

Abstract

Background: Knee osteoarthritis (KOA) is characterized by a gradual wearing away of the cartilage in the joint through strain originating from weight bearing, repeated injury, and/or damage and is one of the most associated causes of knee pain. Current options for pain management include medication or surgery. Consequently patients are alternatively seeking a non-invasive approach that can help manage their pain. Recently, Class IV laser has gained popularity due to its clinical efficacy in pain management and non-invasive application.

Objective: The aim of this randomized control trial was to evaluate the effects of a 30W powered Class IV laser with 1064 nm wavelength on knee pain in the treatment of patients with KOA.

Methods: Patients were randomly assigned into two groups. Each patient underwent 7 treatment sessions every other day. Group-I (Laser group): 30 patients were treated with a semi conductive Class IV Laser with Scanning System applicator (BTL Industries Ltd.) With a maximal power of 30 W and 1064 nm wavelength. Group-II (Control group): 30 patients were treated with the same device without emission from the laser diode, and only a visible navigation beam to act as a placebo. All patients perception of pain was evaluated prior to beginning treatment (baseline), following the first session, after the 7 therapies, and 1 month following the last treatment using the Visual Analogue Scale (VAS).

Results: The Man-Whitney test revealed there was a significant ($P=0.01$) reduction in pain according to the VAS results for the laser group (44.24% improvement), whereas the control group displayed no significant difference (3.93% improvement) in pain perception following the treatment(s).

Conclusion: Class IV laser treatment was found to be an effective modality in reducing knee pain in KOA patients.

Keywords: Knee osteoarthritis; Class IV laser; 1064 nm, Scanning system; Visual analogue scale

Introduction

Knee Osteoarthritis (KOA) is one of the major causes of physical disability that has a social and public health impact [1]. Osteoarthritis is characterized by gradual wearing away of the cartilage in the joint through strain from weight bearing, repeated injury and/or damage. KOA is the most common type of knee arthritis [2]. The major cause of functional impairment and disability in people with KOA is pain [3]. The most common way to treat KOA pain is through the use of medications such as nonsteroidal anti-inflammatory drugs (NSAIDs) and Acetaminophen which can have long-term negative effects including renal and gastric disorders, disturbances in immunological allostasis and inhibited bone healing [4-6]. Surgery is also a viable treatment option when the pain is severe and conservative treatments do not provide much help, but it too creates limitations such as increasing fall risk post-surgery due to deficits in knee extension strength and lower limb proprioception [7,8]. The popularity of the application of laser therapies is increasing due to laser being a non-invasive, painless modality that can be easily administered for a wide range of conditions [9]. Both Class IV laser and Low-Level Laser Therapy (LLLT) have been used in helping treat pain on individuals with KOA. Various studies have looked at the benefits of Class IV laser and its advantage over LLLT. According to Santamato et al., Class IV laser therapy showed to significantly reduce subject's pain based on its analgesic, anti-inflammatory, anti-edematous properties [10].

The major advantage of Class IV laser therapy over LLLT is its high power and wavelengths above 1000 nm which are able to penetrate deeper into joints and muscles for improved medical effects. The higher the power, an increased effectiveness of pulsed analgesic therapy is

observed in acute patients, as well as the delivery of intense thermic therapies for chronic conditions [11]. Additionally, high power allows delivery of the energy to the patient's body within a shorter time, which provides a more practical benefit. Since LLLT can only deliver a small range of power, its benefits tend to be only superficial. Although this may be valuable in treating acne, scars, and superficial muscle, it is unable to penetrate deep into joints and large muscle groups and deliver any heat effect for the patient [12]. It has been recommended that comparing the effect of Class IV laser with placebo control groups should be conducted to measure the functional improvement as a result of pain reduction [11,13-15]. Accordingly, the aim of this study was to evaluate the effects of Class IV laser therapy on knee pain in the treatment of patients with KOA.

Materials and Methods

Inclusion criteria

Prior to starting the study, confirmation of patients diagnosed with KOA was ratified by medical doctors, Physical Medicine and Rehabilitation, and supplemented by health records. An age range of

*Corresponding author: Bettencourt F, Department of Medical Sporting Clube de Portugal, ComCorpus Clinic, Lisbon, Portugal, E-mail: bettencourt.oliveira@gmail.com

Received December 02, 2019; Accepted January 22, 2020; Published January 27, 2020

Citation: Bettencourt F (2020) Effects of Class IV Laser in Knee Osteoarthritis: A Randomized Control Trial. J Arthritis 9: 289.

Copyright: © 2020 Bettencourt F. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

40-60 was used since KOA is commonly observed in older populations [16]. Additional patient inclusion criteria for this study included:

- Patient had painful KOA for at least 6 months with degenerative osteoarthritic knee symptoms in accordance to the Kellgren and Lawrence classification system [17].
- He did not engage in any high-joint-loading exercises such as tennis.
- Patient had not undergone any surgery or physical modalities 3 months before entering the study.
- He had a minimum total score of 25 on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) when evaluated by a medical doctor [18].
- He had a knee pain ≤ 4 on the Visual Analogue Scale (VAS) in the past 3 months [19,20]. All skin types were included in the study.

Exclusion criteria

Patients were excluded from the study if they underwent previous knee surgery, had central or peripheral neuropathy, were pregnant, and/or had a malignant tumor. Additionally, patients who experienced acute or subacute knee inflammation from recent impact trauma such as a fall, and therefore not the cause of KOA, prior to or during the study were also excluded as to avoid misinterpreted data.

Study design

The study was designed as a single blind randomized control trial. Patients were randomized into 2 groups (n=60). Randomization was performed by block randomization using a computer-generated algorithm. Patients did not know to which group they were assigned or which treatment they would be offered.

Ethical standards

All participants were informed about the study protocol and each gave written informed consent for study participation and for publication of the results. Furthermore, the treatment method was consistent with the ethical guidelines of the 1975 Declaration of Helsinki adopted by the General Assembly of the World Medical Association (1997-2000) and by Convention on Human Rights and Biomedicine of the Council of Europe (1997) [21,22].

Therapy device

A Semi conductive Class IV Laser with a Scanning System applicator (BTL Industries Ltd.) consisting of a maximal power of 30 W and 1064 nm wavelength was used in the laser group. The control group underwent a placebo sham treatment which used the same Class IV laser device consisting of a visible and operational navigation beam, however the emission from the laser diode was turned off.

Therapy procedure

Applications were common for both groups, laser was applied medially to laterally on the patient's knee while in a supine position on a cushioned treatment table. The treated knee was slightly flexed and supported by a firm orthopaedic knee pillow to promote knee stability during treatment. All patients and operators wore safety eyewear for eye protection.

Therapy parameters

Treatment was performed every other day, with 7 sessions in total.

Laser therapy was applied from the medial to lateral side of the knee, using a 10 mm diameter of the laser beam and ensuring a controlled distance of 20 cm between the laser output and treatment area of 5 × 5cm. For the laser group the first phase treatment lasted 1 minute and consisted of a pulsed emission with an application dosage of 6 Joules (J). The second phase treatment lasted 7 minutes and consisted of a continuous emission with an application dosage of 80 J. It is also important to note that the area and heat tolerance of the knee can differ for each individual, therefore the laser power was adjustable if individuals were experiencing too much of a heat effect.

Pain evaluation

A Visual Analogue Scale (VAS) was used to measure the subjective perception of pain intensity. The scale consists of a 10 cm line divided into 10 equal sections, with 0 representing “no pain” and 10 representing “unbearable pain.” Each participant was asked to indicate on the scale the level of pain in the affected knee joint before the initial intervention (baseline), after the first therapy, after 7 therapies, and 1 month following the last experimental treatment.

Statistical analysis

The Shapiro-Wilk normality test was performed to determine the data distribution in order to verify which statistical test should be used. The negative result of the Shapiro-Wilk test and low number of patients lead to the use of a non-parametric test. Each group's VAS results were analysed by Mann-Whitney U-test on the level of P=0.01 to compare between baseline and the difference between VAS scores after the 1st therapy, 7th therapy and 1 month post-therapy.

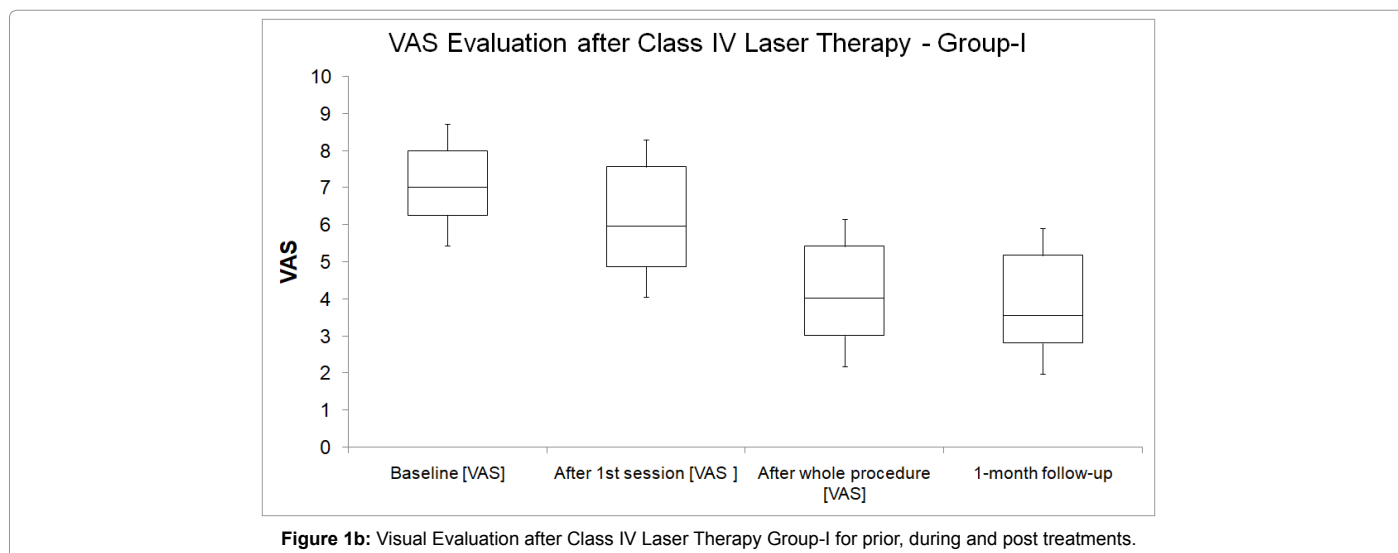
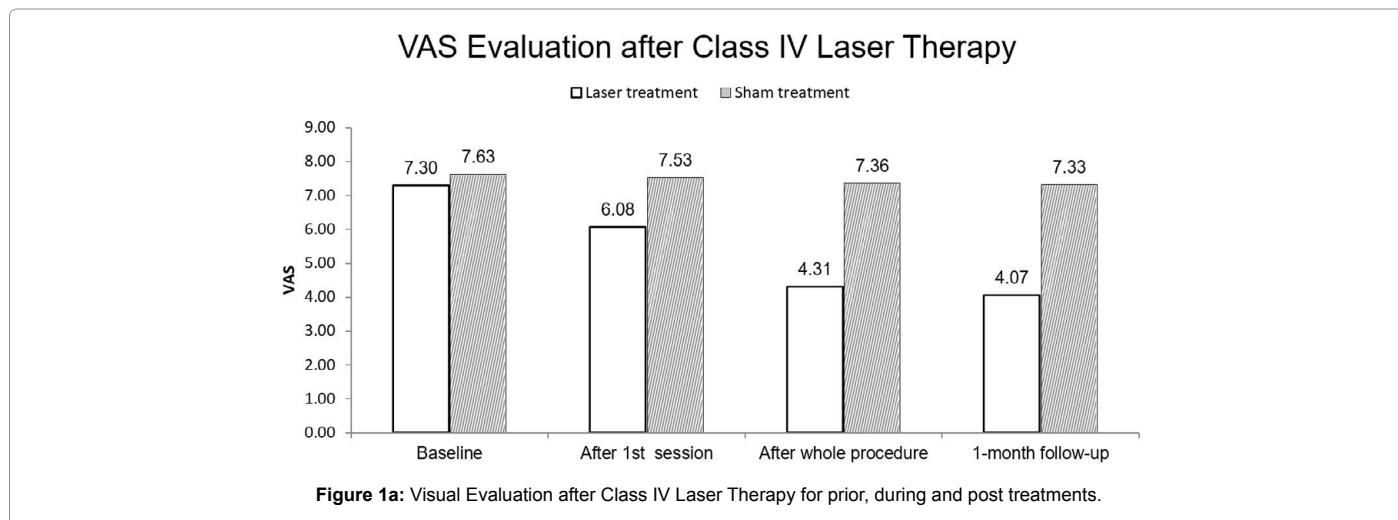
Results

A total of 60 patients were randomized into two groups. Laser therapy group (n=30) received treatment with Class IV laser and the control group (n=30) received the sham intervention. Baseline characteristics of the patients are shown in Table 1. Both of these groups did not report any side effects or problems following any of the treatments. The Mann-Whitney test was used to compare the laser and control groups baseline, post-treatment, and 1-month follow-up scores of the VAS (p<0.01) results. An average power output of 15 ± 1.16 W for all patients was used during the continuous emission phase and 30W during the pulsed emission phase. No variation occurred for the pulsed 30 W output since no significant thermal effects were produced during the pulsed therapy procedure, which was intermittent and therefore easily tolerated without any heat discomfort from all patients. VAS baseline results of the laser group 7.30 ± 1.09 and control group 7.63 ± 1.10 respectively showed nonsignificant (p<0.01) differences (Table 2 and Figure 1a). No significant (p<0.01) difference was observed for the control group in the pain (7.53 ± 1.09) after the first intervention. Furthermore no significant difference (p<0.01) was observed after 7 sessions (7.46 ± 1.82) according to the VAS scores (Table 2 and Figure 1a).

A significant (p<0.01) difference was found in the laser group while evaluating knee pain (6.11 ± 1.65) after the first intervention. From

Baseline characteristics		
Gender	Laser group	Sham group
Females	15 (50.0%)	17 (56.6%)
Mean age-Females	52 ± 4.73	53 ± 5.10
Males	15 (50.0%)	13 (43.4%)
Mean age-Males	52 ± 4.62	54 ± 5.11
Average therapy power in continuous mode [W]	15 ± 1.16	0.03 ± 0.002

Table 1: Baseline characteristics of the patients.



baseline (7.30 ± 1.09) the pain significantly ($p < 0.01$) decreased to (4.18 ± 1.89) after the last intervention (Table 2, Figures 1a and 1b). A one month follow up was also conducted for all subjects to observe if there was any long-term benefit of the Class IV laser treatment. A significant ($p < 0.01$) difference was found in the laser group while evaluating knee pain (4.07 ± 1.75) following the first month post treatment, whereas for the control group showed no significant difference in knee pain (7.33 ± 1.04) (Table 2 and Figure 1a).

Discussion

The aim of this study was to evaluate the effects on pain using a Class IV laser with a 1064 nm wavelength and 30W maximal power output, which is the first study to our knowledge that has used such parameters. Despite these different parameters, the underlying principles of laser therapy are the same in previously performed laser therapy studies [11-24]. Our measurement results provide evidence that treatment with this Class IV laser had a significant effect on decreasing the VAS score of knee pain in KOA patients compared to the control group. This further supports the notion that Class IV laser, in accordance with these parameters of 1064 nm and 30 W powers, could be an important modality for treating patients with KOA due

Outcome measure	Laser group	Sham group
Baseline	7.30 ± 1.09	7.63 ± 1.10
Pain after the first session	6.11 ± 1.65	7.53 ± 1.09
Pain after the whole procedure	4.18 ± 1.89	7.46 ± 1.82
Pain 1-month follow-up	4.07 ± 1.75	7.33 ± 1.04

Table 2: Outcome measurements.

to a significant reduction in pain. We acknowledge that the following study has certain limitations, which include the absence of comparing Class IV Laser to other regular physiotherapy modalities/options such as heat/ice packs or analgesics.

It is important to note that although the VAS scale is a subjective tool in assessing pain, it is commonly used among studies involved in applying laser therapies and measuring pain perceptions for individuals with KOA due to its availability and ease to administer [10-25]. Furthermore, the implementation of seven treatment sessions were justified by studies by Angelova et al. [13] and Ciplak et al. [26], which met the requirement to obtain a significant result regarding Class IV lasers on pain efficacy. In order to better understand the reduction of pain on our KOA patients we need to understand the mechanisms

behind laser therapy. Laser therapies are shown to reduce the inflammatory process by altering prostaglandin synthesis, decreasing interleukin 1, enhancing lymphocyte response, and decreasing C-reactive protein and neopterin levels [27,28]. Additionally, they can reduce pain at the tissue level by altering the release of chemical mediators such as histamine and bradykinin, which are released from injured tissues [28]. Both histamine and bradykinin act to inhibit the release of substance P, in turn decreasing the threshold of pain [29,30].

Previous studies that applied Class IV laser therapy on subjects with KOA alongside the VAS scale concluded that laser diode emission can reduce pain indirectly by increasing microcirculation [31], increasing oxygenation to tissues, reduce knee swelling [32] and decrease the intensity of inflammation. We justified using a 1064 nm wavelength based on its ability to penetrate into deeper tissues and reduce pain and inflammation in deeper areas such as the knee joint. Studies by Gur et al. [33] and Tascioglu et al. [24], support the notion that using wavelengths under 1000 nm, 904 nm and 830 nm respectively, showed no significant effect on pain reduction in patients with KOA. The use of a maximal power output of 30W was used based on two major factors. Firstly, when working with higher power compared to LLLT, the higher the power the more energy can be delivered to the specific treatment area in a shorter time span. This is beneficial for both the therapist and patient as therapy time is reduced to deliver a specific dose of laser energy when compared to a lower powered device which will have a longer duration to deliver the same amount of energy [34]. Secondly, high power output allows for the application of a thermic effect to the treated area which is helpful for chronic patients [35]. Specifically, the higher the power for acute patients, the better efficacy of the pulsed analgesia. Moreover, Gur et al. [33] and Tascioglu et al. [24] also concluded that low power outputs of 11.2 or 50 mW were insufficient in producing a thermal effect. This demonstrates that power output and wavelength are important factors in laser therapies [27]. The application of Class IV laser with a wavelength (>1000 nm) over a longer period of time produces a higher therapeutic dosage, which is delivered to the tissue and can stimulate the tissues effectively for treating pain and decreasing inflammation.

Conclusion

Class IV laser therapy with a single 1064 nm wavelength and 30 W power is an effective modality in the treatment of patients with KOA pain based on its analgesic, anti-inflammatory, anti-edematous properties. The results of the present study are encouraging but other studies with larger samples, comparisons with other conservative interventions, and post treatment follow ups should be implemented to better understand the long term effects of Class IV laser therapy. For these reasons, continued research in this area is therefore of great importance.

References

- Felson DT, Zhang Y (1998) An update on the epidemiology of knee and hip osteoarthritis with a view to prevention. *Arthritis Rheum* 41: 1343-1355.
- Kulchitskaya DB, Konchugova TV, Fedorova NE (2017) Comparative evaluation of the effects of high-intensity and low-intensity laser radiation on microcirculation among patients with knee arthritis. *Journal of Physics: Conference Series* 826: 012015.
- Creamer P, Lethbridge-Cejku M, Hochberg MC (2000) Factors associated with functional impairment in symptomatic knee osteoarthritis. *Rheumatology* 39: 490-496.
- Mora JC, Przkora R, Cruz-Almeida Y (2018) Knee osteoarthritis: pathophysiology and current treatment modalities. *Journal of pain research* 11: 2189-2196.
- Van Esch RW, Kool MM, van ASS (2013) NSAIDs can have adverse effects on bone healing. *Medical Hypotheses* 81: 343-346.
- Nagai J, Uesawa Y, Shimamura R, Kagaya H (2017) Characterization of the Adverse Effects Induced by Acetaminophen and Nonsteroidal Anti-Inflammatory Drugs Based on the Analysis of the Japanese Adverse Drug Event Report Database. *The Clinical Journal of pain* 33: 667-675.
- McAlindon TE, Bannuru RR, Sullivan, MC, Arden NK, Berenbaum F, et al. (2014) OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis and Cartilage*, 22: 363-388.
- Levinger P, Menz HB, Wee E, Feller JA, Bartlett JR, et al. (2010) Physiological risk factors for falls in people with knee osteoarthritis before and early after knee replacement surgery. *Knee Surgery, Sports Traumatology, Arthroscopy*, 19: 1082-1089.
- Kim GJ, Choi J, Lee S, Jeon C, Lee K (2016) The effects of high intensity laser therapy on pain and function in patients with knee osteoarthritis. *Journal of Physical Therapy Science* 28: 3197-3199.
- Santamato A, Solfrizzi V, Panza F, Tondi G, Frisardi V, et al. (2009) Short-term Effects of High-Intensity Laser Therapy Versus Ultrasound Therapy in the Treatment of People With Subacromial Impingement Syndrome: A Randomized Clinical Trial. *Physical Therapy* 89: 643-652.
- Kheshie AR, Alayat MSM, Ali MME (2014) High-intensity versus low-level laser therapy in the treatment of patients with knee osteoarthritis: a randomized controlled trial. *Lasers in Medical Science* 29: 1371-1376.
- Hopkins JT, McLoda TA, Seegmiller JG, David Baxter G (2004) Low-Level Laser Therapy Facilitates Superficial Wound Healing in Humans: A Triple-Blind, Sham-Controlled Study. *Journal of Athletic Training* 39: 223-229.
- Angelova A, Ilieva EM (2016) Effectiveness of High Intensity Laser Therapy for Reduction of Pain in Knee Osteoarthritis. *Pain Research and Management* 2016: 1-11
- Stiglic-Rogoznica N, Stamenkovic D, Frlan-Vrgoc L, Avancini-Dobrovic V, Vrbancic TS (2011) Analgesic effect of high intensity laser therapy in knee osteoarthritis. *Coll Antropol* 35:183-185.
- Yurtkuran M, Alp A, Konur S, Ozçakir S, Bingol U (2007) Laser Acupuncture in Knee Osteoarthritis: A Double-Blind, Randomized Controlled Study. *Photomedicine and Laser Surgery* 25: 14-20.
- Chen DY (2007) Updated Therapy in Elderly Patients with Knee Osteoarthritis. *International Journal of Gerontology* 1: 31-39.
- Kellgren JH, Lawrence JS (1957) Radiological assessment of osteo-arthrosis. *Annals of the rheumatic diseases* 16: 494-502.
- Bellamy N, Watson Buchanan W, Goldsmith CH, Campbell J, Stitt LW (1988) 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 or the knee. *J Rheumatol* 15: 1833-1840.
- Hunter DJ, Eckstein F(2009) Exercise and osteoarthritis. *Journal of Anatomy* 214: 197-207.
- White DK, Felson DT, Niu J, Nevitt MC, Lewis CE, et al. (2011) Reasons for functional decline despite reductions in knee pain: the Multicenter Osteoarthritis Study. *Physical therapy*, 91: 1849-1856.
- World Medical Association Declaration of Helsinki (1997) *JAMA* 277: 925.
- Council of Europe (1997) Convention for Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Biomedicine: Convention on Human Rights and Biomedicine. *Kennedy Institute Of Ethics Journal* 7: 277-290.
- Youssef EF, Muaidi QI, Shanb AA (2016) Effect of Laser Therapy on Chronic Osteoarthritis of the Knee in Older Subjects. *Journal of Lasers in Medical Sciences* 7: 112-119.
- Tascioglu F, Armagan O, Tabak Y, Corapci I, Oner C (2004) Low power laser treatment in patients with knee osteoarthritis. *Swiss Med* 134: 254-258.
- Alayat MSM, Atya AM, Ali MME, Shosha TM (2013) Long-term effect of high-intensity laser therapy in the treatment of patients with chronic low back pain: a randomized blinded placebo-controlled trial. *Lasers in Medical Science*, 29: 1065-1073.
- Ciplak E, Akturk S, Buyukavci R, Ersoy Y (2018) Efficiency of high intensity laser

-
- therapy in patients with knee osteoarthritis. *Medicine Science | International Medical Journal* 7: 724-727.
27. Farivar S, Malekshahabi T, Shiari R (2014) Biological effects of low level laser therapy. *Journal of lasers in medical sciences* 5: 58-62.
28. Ash C, Dubec M, Donne K, Bashford T (2017) Effect of wavelength and beam width on penetration in light-tissue interaction using computational methods. *Lasers in medical science* 32: 1909-1918.
29. Navratil L, Dylevsky I (1997) Mechanisms Of The Analgesic Effect Of Therapeutic Lasers In Vivo. *Laser Therapy* 9: 33-39.
30. Klebanov GI, Kreinina MV, Poltanov EA, Khristoforova TV, Vladimirov YA (2001) *Bulletin of Experimental Biology and Medicine* 131: 239-241.
31. Hegedus B, Viharos L, Gervain M, Galfi M (2009) The Effect of Low-Level Laser in Knee Osteoarthritis: A Double-Blind, Randomized, Placebo-Controlled Trial. *Photomedicine and Laser Surgery* 27: 577-584.
32. Nakamura T, Ebihara S, Ohkuni I, Izukura H, Harada T, et al. (2014) Low Level Laser Therapy for chronic knee joint pain patients. *Laser Therapy* 23: 273-277.
33. Gur A, Cosut A, Jale Sarac, A, Cevik R, Nas K, et al. (2003) Efficacy of different therapy regimes of low-power laser in painful osteoarthritis of the knee: A double-blind and randomized-controlled trial. *Lasers in Surgery and Medicine* 33: 330-338.
34. Enwemeka CS (2009) Intricacies of Dose in Laser Phototherapy for Tissue Repair and Pain Relief. *Photomedicine and Laser Surgery* 27: 387-393.
35. Carroll L, Humphreys TR (2006) LASER-tissue interactions. *Clinics in Dermatology* 24: 2-7.