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Impact of high-power laser therapy on bilateral knee osteoarthritis: A randomized trial

Wpływ terapii laserowej wysokiej mocy na obustronną osteoartrozę kolan: Badanie randomizowane

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Abstract

Background. Osteoarthritis is the most common type of arthritis. It is the main cause of chronic musculoskeletal pain and disability, it decreases the flexibility of the joint, and causes pain, joint effusion and loss of function among the elderly population.

Objective. To examine how HILL therapy (High intensity laser therapy NDYAG 1064 nm) affects knee osteoarthritis.Design. A prospective randomized controlled trial. Setting. Outpatient Swiss physical therapy center.

Methods. Thirty patients of both gender having bilateral knees osteoarthritis were recruited and randomized into two equal groups: the control group received a program of selected quadriceps muscle sets exercise and hamstring, calf muscles stretching for 4 weeks, and the study group received the same control group interventions in addition to HILL application. Ultrasonography degree was the primary outcome, While Western Ontario and McMaster universities (WOMAC) osteoarthritis index measures were the secondary outcomes. All variables were measured at the baseline and after 4 weeks of the intervention.

Results. Statistical analysis was done by using paired' test which showed significant improvement in both groups. Therefore, there was a significant difference between Group(A) and Group(B), showing that HILL group(A) is more effective than group(B) on pain, Stiffness, Function and ultrasonographic findings ($p < 0.05$).

Conclusion. Using HILT with a standard program of quadriceps muscle strengthen exercise sets and hamstring, calf muscles stretching has more beneficial effects on bilateral knee osteoarthritis than practicing the exercise program alone.

Keywords

knee osteoarthritis, high power laser, physical exercise, ultrasonography

Streszczenie

Osteoartroza jest najczęstszym typem zapalenia stawów. Jest główną przyczyną przewlekłego bólu mięśniowo-szkieletowego i niepełnosprawności, zmniejsza elastyczność stawu oraz powoduje ból, wysięk stawowy i utratę funkcji wśród osób starszych. Cel. Zbadanie wpływu terapii laserowej o wysokiej intensywności NDYAG 1064 nm (HILL) na osteoartrozę kolan. Projekt badania. Prognozowane randomizowane badanie kontrolowane. Miejsce. Szwajcarskie ambulatoryjne centrum fizjoterapii. Metody. Trzydziestu pacjentów obu płci z osteoartrozą obu kolan zostało rekrutowanych i losowo przydzielonych do dwóch równych grup: grupa kontrolna otrzymała program ćwiczeń wybranych zestawów mięśni czworogłowych uda oraz rozciągania mięśni łydek i podkolanowych przez 4 tygodnie, a grupa badawcza otrzymała te same interwencje co grupa kontrolna, dodatkowo z zastosowaniem terapii HILL. Głównym wynikiem było określenie stopnia zmian za pomocą ultrasonografii, natomiast wtórnymi miarami były indeksy osteoartrozy Western Ontario i McMaster University (WOMAC). Wszystkie zmienne mierzono na początku i po 4 tygodniach interwencji. Wyniki. Analiza statystyczna została przeprowadzona przy użyciu testu sparowanego, który wykazał znaczną poprawę w obu grupach. W związku z tym istniała znacząca różnica pomiędzy grupą (A) a grupą (B), pokazując, że grupa HILL (A) jest bardziej skuteczna niż grupa (B) w zakresie bólu, sztywności, funkcji i wyników ultrasonograficznych ($p < 0,05$). Wnioski. Użycie HILT w połączeniu ze standardowym programem ćwiczeń wzmacniających mięśnie czworogłowe uda oraz rozciągania mięśni łydek i podkolanowych ma bardziej korzystny wpływ na osteoartrozę obu kolan niż samodzielne wykonywanie programu ćwiczeń.

Słowa kluczowe

osteoartroza kolan, laser wysokiej mocy, ćwiczenia fizyczne, ultrasonografia

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Introduction

Osteoarthritis (OA) is a chronic multifactorial disease characterized by progressive joint degeneration accompanied by subchondral bone sclerosis which can lead to the formation of bone cysts and marginal osteophytes [1]. Besides these intrinsic changes of the joints, other signs such as decreased knee flexibility, pain and joint effusion, crepitus, deformities, and loss of function are often present [2]. The exact etiology of knee OA remains unclear, but it is frequently associated with repetitive microtraumas, previous knee surgery, metabolic or endocrinological factors, heredity, obesity and joint overload [3]. Radiographic findings include joint space narrowing, osteophyte formation, subchondral sclerosis and cysts [4]. It is a leading musculoskeletal cause of disability in elderly persons all over the world and a major cause of physical limitations and reduced quality of life. In the United States and according to the World Health Organization, it is estimated that 10% of the world population over 60 years of age has symptomatic knee OA [5]. And that 12% of adults aged 65 years and older have symptomatic knee OA. The prevalence of knee OA increases with age and is more common in women than in men [6]. The disease has a progressive impact upon activities of daily living, ultimately leading to a progressive loss of functional independence and deterioration of quality of life. Current clinical guidelines recommend non-pharmacological strategies as the first line management of OA symptoms [7]. Interventions have typically focused on symptomatic relief and improvement of functional status [8]. As well as lifestyle modification, weight reduction, drugs, surgery, and rehabilitation interventions such as exercises and physical agents [9]. The most common way to treat KOA pain is through the use of medications such as non-steroidal anti-inflammatory drugs (NSAIDs) and Acetaminophen which can have long-term negative effects including renal and gastric disorders, disturbances in immunological and inhibited bone healing.Surgery is also a treatment option when the pain is severe and conservative treatments do not provide much help, but it too creates limitations such increasing fall risk post-surgery due to deficits in knee extension strength and lower limb proprioception[10]. Limitation of joint motion is usually related to osteophyte formation, severe cartilage loss or periarticular muscle spasm and contracture. Periarticular muscle weakness is common and may contribute to progression of KOA through decreased neuromuscular protective mechanisms and functional joint instability [11].

Laser therapy is based on the belief that laser radiation (and possibly monochromatic light in general) is able to alter cellular and tissue functions in a manner that is dependent on the characteristics of the light itself (e.g., wavelength, coherence)[12]. The first source of laser was established in 1960. by T.H. Maiman. In the seventies, laser started being successfully used, first in surgery and afterwards as a healing method and as a consequence the term laser therapy has been introduced. More recently, high-intensity laser therapy (HILT), which involves higher-intensity laser radiation and which causes minor and slow light absorption by chromophores, has been used. This absorption is obtained not with concentrated light but with diffuse light in all directions (the scattering phenomenon), increasing the mitochondrial oxidative reaction and adenosine triphosphate, RNA, or DNA production (photochemistry effects) and resulting in the phenomenon of tissue stimulation (photobiology effects). The analgesic effect of HILT is based on different mechanisms of action, such as slowing down the transmission of pain stimulus and increasing the production of morphine-mimetic substances [13]. Another mechanism of action is based on tissue stimulation. This stimulation forms at cell, vascular tissue, interstitial tissue and immune system level. It increases regeneration and beta-endorphin release by inducing the protein synthesis in synovial fluid, thus it shows analgesic and anti-inflammatory effect [14]. so, the goal of our study was to assess the impact of High intensity laser therapy on knees osteoarthritis.

Materials and methods

Participants

This study was under taken on 30 of bilateral knees osteoarthritis patients. They referred by Orthopedic surgery consultant to Swiss physical therapy center, Giza, Egypt. They were between the ages of 50 and 65. They had a body mass index (BMI) of 29.8 to 50.1 kg/m^2.

Any participant was excluded if she/he had any previous knee surgery, had tendon or meniscus rupture, had central or peripheral neuropathy, had received physical treatment or intra articular corticosteroids or hyaluronic acid injection within the last 6 months, had malignancy. Women who were pregnant also excluded.

Study design and randomization

A randomized, double-blind, pre-posttest trial was used in this research. A simple drawing of lots (A or B) determined whether participants would get high intensity laser therapy, quadriceps muscle strengthening exercise and stretching hamstring, calf groups muscles (group A) or quadriceps strengthening exercise and stretching hamstring (group B) during the randomization phase. The randomization technique was conducted using computer software (Microsoft Excel 2010) that generated a randomized table of numbers, each of which matched to one of the two groups (A or B). Following that, participants were assigned to groups based on the number of their allocation codes. To select which will be in group A or group B, a researcher performed the drawing procedures without telling participants or evaluators. As a result, blinding of the treatment allocation was used for both patients and the evaluators.

Ethical considerations

Before the study began, Ethical approval was obtained from Research Ethics Committee of the National Institute of Laser Enhanced Sciences, Cairo university, Egypt. The ethical committee clearance and informed consent of the subjects were taken. patients have all rights to withdraw from the study at any time with¬out any responsibility.

Study methods instrumentation

Laser machine stricture: Laser medium: solid state lasers, infrared radiation-NDYAG (neodymium-doped yttrium aluminum garnet), Model & manufacture: XP focus device (69283) Fotona company (Slovenia, EU. Wavelength: 1064 nm, Average power: 10 W, Mode: pulsed type, Spot diameter: 8 mm, Width 10 ms, Frequency 1-3 Hz, Energy dose 10 J.

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Thermometer: Fluke 62 max (China).
Assessment procedures: complete medical history will be checked including age, weight, and height and body mass index (BMI). Western Ontario and McMaster Universities (WOMAC) osteoarthritis index, Ultrasonography device: Model: echo2 V.1.8 chison (China). All patients will be assessed before and after the treatment program.

Procedures
The control group (B) involved 15 bilateral knees osteoarthritis patients who followed exercises program that consisted of quadriceps strengthening exercise (open chain progression isometric type) in addition to calf and hamstring muscles groups stretching, the duration of exercises lasted 20 minutes 3 times a week for 4 weeks and as a home routine. The study group (A) included 15 bilateral knees osteoarthritis patients who followed same exercises, as the control group, in addition to HILL application using NDYAG 1064 nm 10 J. Application of HILL was 3 sessions per week for 4 weeks).
All the patients in both groups followed the same exercise program. The first component of the program was quadriceps strengthening exercise (open chain progression isometric type) Patients lay in a supine position. A rolled-up towel was put beneath the knee. They were instructed to maximally activate their thigh muscles in order to straighten their knee and hold the contraction for 5 seconds. Straight leg raising (SLR) exercise: Patients lay in a supine position. They were instructed to perform a maximum isometric quadriceps contraction prior to the lifting phase of the exercise. Then they were instructed to lift the leg up to 10 cm above the plinth and hold the contraction during the lifting phase for 10 seconds, followed by calf muscle group stretch: patient assumes a standing position with involved lower extremity placed behind the non-involved. Patient 'arms are placed on the wall and involved knee is kept straight with heel flat to the floor until stretch is felt and hamstring muscle group stretch: Patient is positioned in sitting position. Affected leg is kept straight and patients attempts to reach towards the toes keeping the low back in a neutral position until a stretch is felt.
For the study group, High-power laser therapy will be performed by high level laser therapy (HLLL) device. Laser machine strictture: Laser medium: solid state lasers, infrared radiation-NDYAG (neodymium-doped yttrium aluminum garnet), Model & manufacture: XP focus device (69283) Fotona company (Slovenia, EU. Wavelength: 1064 nm, Average power: 10 W, Mode: pulsed type, Spot diameter: 8 mm, Width 10 ms, Frequency 1 Hz, Energy dose 10 J. During all therapy sessions, the physiotherapist and the patient wore protective glasses, and the treatment area is locked, with limited access and no reflective surfaces.
The first six sessions were analgesic effect with dose 300 J accumulative with 1 Hz frequency, for the treated area of 25 cm^2. The probe moved 1cm/ second from a starting point to an endpoint repeatedly during the treatment period at knee points bilaterally, Sixty points of irradiation on medial and lateral sides of the knees area perpendicular to the body surface. At the next 6 sessions, bio stimulation parameter applied with dose 3000 J accumulative on treated area of 25 cm^2 applied on the medial side of the knee joint. The skin temperature measured during the session not to exceed 40°C to avoid skin burn used thermometer (Fluke 62 max, Fluke corporation. China). In the study, laser radiation is applied with analgesic parameters on two opposite fields, because, at the selected stages of osteoarthritis of the knee, all intraarticular and periarticular tissues are involved in the process; thus, nociceptive signals are generated by different structures.
Bio stimulation parameters were administered on the medial field because predominantly the medial compartment of the joint is usually affected. This is predetermined by anatomical features, axis load, Q-angle, and rotation of the medial condyle of the knee in the last degrees of the range of motion.

Outcome measures
Each subject in both groups was evaluated before treatment and after the intervention.

Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Inde
It consists of three sections as pain, stiffness and physical function and totally 24 questions. The increase of this value shows that pain and stiffness increase and physical function impairs [15].

Ultrasound image
Diagnostic ultrasound is an ultrasound-based diagnostic imaging approach for determining Joint effusion, which was placed longitudinally on the suprapatellar pouch, and we determined the area (mm^2) of the echo-free space. When the knee flexes from extension, the fluid in the anterior knee will be redistributed. More fluid will shift to the suprapatellar recess and medial parapatellar recess. Therefore, it is easier to detect an effusion longitudinally in the suprapatellar recess and the medial parapatellar recess when the knee is in flexion. An international study on knee effusion showed that the longitudinal scan of the suprapatellar recess with 30 degrees flexion of the knee is the best position for detection of knee effusion compared to scans of the lateral parapatellar and medial parapatellar recesses with the knees at different (0°, 15°, 30°, 45°, 60°, and 90°) degrees of flexion [16].

Weight and BMI
Weight was measured by valid and reliable device and BMI was calculated.

Statistical analysis
The scores of rates of pain, Rate of stiffness, Rate of difficulty and ultrasonographic findings in each group before and after the treatment were compared with paired-sample t-test. The change between the two groups measured before and after physiotherapy was analyzed. A statistical significance was known as p-value < 0.05
We ran all of our numbers through SPSS for Windows, version 26 of the Statistical Package for the Social Sciences. Shapiro-Wilk test was used to look for signs of covariance homogeneity and test for normality in the data, respectively.

Results
Table 1 showed the demographic characteristics of both groups. There was no significant difference between both groups in the mean age, weight, height, BMI. ($p > 0.05$).

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Table 1. Mean and standard deviation of age, weight, height, BMI for both groups

	Tests of Normality					
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Age	0.128	30	0.200	0.965	30	0.412
Weight	0.131	30	0.200*	0.977	30	0.733
Length	0.076	30	0.200*	0.984	30	0.910
BMI	0.107	30	0.200*	0.974	30	0.658

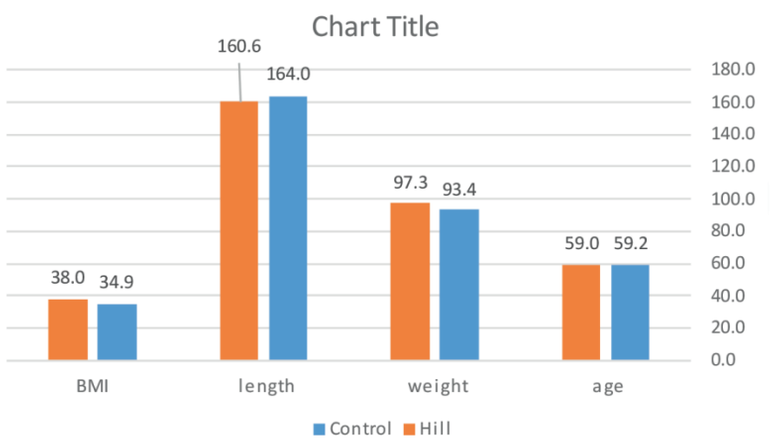

Table 2 showed the demographic characteristics of group (A). There was significant difference between rates of pain, Stiffness, Difficulty and ultrasonographic findings pre and post treatment of HILL. ($p > 0.05$).

Table 2. T-test (Non -independent) Rates of pain, Stiffness, Difficulty and ultrasound image

HILT	pre		post		T Test	SIG	Effect Size
	Mean	Std. Deviation	Mean	Std. Deviation			
WOMAC Pain rates	2.480	0.413	0.933	0.533	10.276	0.000	1.94
WOMAC Stiffness rates	2.367	0.611	0.900	0.687	8.876	0.000	1.68
WOMAC Difficulty rates	2.639	0.259	1.035	0.531	12.052	0.000	2.28
Ultrasonographic finding rates	5.418	0.569	2.154	0.657	22.934	0.000	4.33

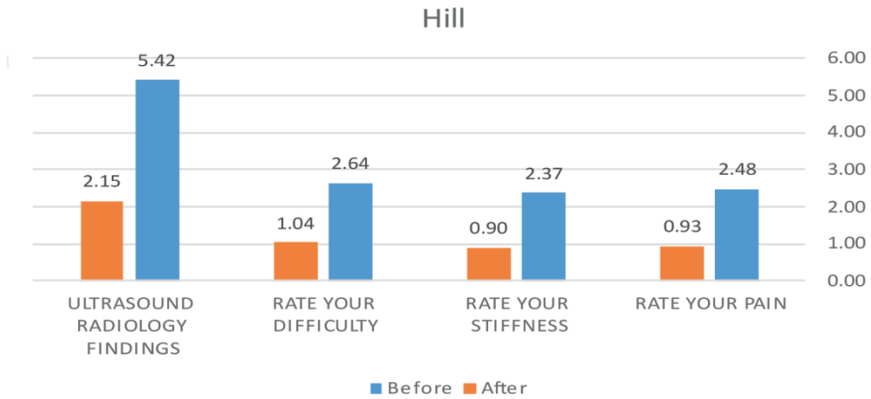

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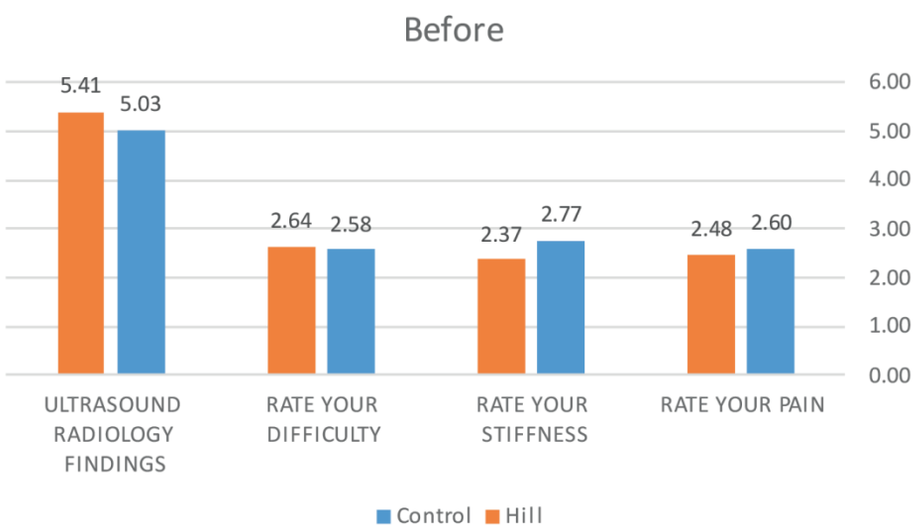
Table 3. T-test (Non -independent) Rates of pain, Stiffness, Difficulty and ultrasound image

CONTROL GROUP	pre		post		T Test	P Value
	Mean	Std. Deviation	Mean	Std. Deviation		
WOMAC Pain rates	2.600	0.370	2.213	0.475	4.490	0.001
WOMAC Stiffness rates	2.767	0.704	2.333	0.794	5.245	0.000
WOMAC Difficulty rates	2.580	0.210	2.188	0.247	12.987	0.000
Ultrasonographic finding rates	5.029	0.749	4.621	0.736	3.020	0.009

The descriptive data for the impact of treatments on all dependent variables are shown in Table (4). WOMAC rates for pain, stiffness, difficulty and Ultrasound findings were all shown to decrease significantly ($p < 0.05$) in both groups post treatment, as determined by multiple pairwise comparison tests comparing pre- and post-treatment data. Multiple pairwise comparisons between the two groups before and after treatment. but there was a significant decrease ($p < 0.05$) in favor of group (A) compared to group (B) in terms of pain rates, stiffness rates, difficulty rates and ultrasonographic findings. Therefore, there is a significant difference between Group(A) and Group(B), showing that high intensity laser therapy (HILL)in addition to quadriceps muscle strengthening exercise and stretching hamstring, calf groups muscles is more effective than exercise only (control group) on bilateral knees osteoarthritis ($p < 0.05$).

Table 4. T-test (independent) Rates of pain, Stiffness, Difficulty and ultrasound image post treatment of both groups

GROUP		N	Mean	Std.	Deviation	T Test	ETA
WOMAC Pain rates	HILL CONTROL	15 15	0.933 2.213	0.533 0.475	6.946	0.633	1.31
WOMAC Stiffness rates	HILL CONTROL	15 15	0.900 2.333	0.687 0.794	5.287	0.500	1.00
WOMAC Difficulty rates	HILL CONTROL	15 15	1.035 2.188	0.531 0.247	7.624	0.675	1.44
Ultrasonographic finding rates	HILL CONTROL	15 15	2.154 4.621	0.657 0.736	9.501	0.763	1.80



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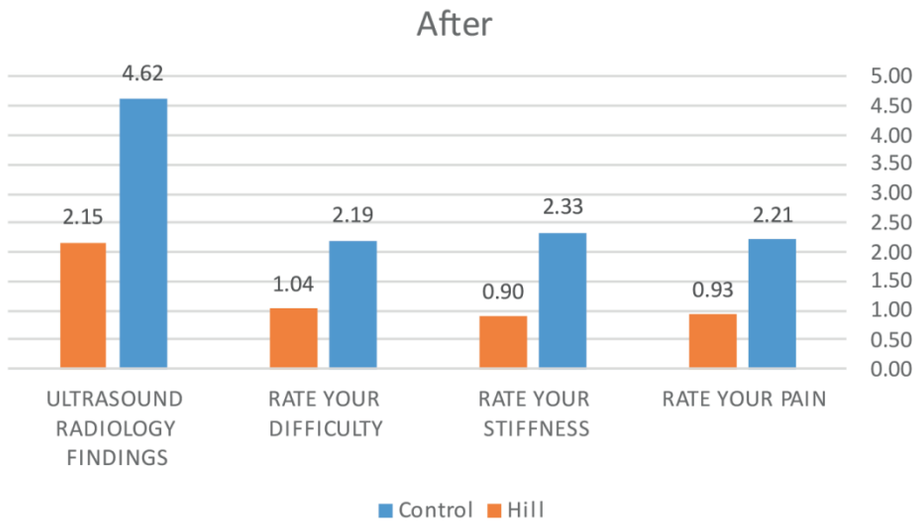

Discussion

Our study's major goal was to see how HILL therapy affected on bilateral knees osteoarthritis. The results showed that the study group had a significant reduction in pain, stiffness and difficulty, ultrasound measurements pre and post treatment and Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index between groups. In the present study, the results were obtained after12 HILT treatment sessions over a period of 2 consecutive weeks in patients diagnosed with KOA. The understanding of the pathogenic mechanisms and pathoanatomic changes in osteoarthritis raises the need of new therapeutic interventions in the process. The degeneration of the cartilage was found to be a result of intensive mechanical stress and lysis with the participation of mediators such as metalloproteinases, synthesized by chondrocytes: interleukin-1, prostaglandin E2, and proteinases 1, 3, and 13 [17]. The predominance of degradation process is a prerequisite for the development of osteoarthritis. In vitro studies found that this process could be modified by the application of growth factors of chondrocyte cultures, but these findings have not been proved in in vivo studies [18, 19]. In OA there is functional inadequacy of the chondrocytes to synthesize the main components of the extracellular matrix and the collagen fibrils with quality, necessary to fulfil its primary biological role, hydrophily, elasticity, and compressively of cartilage hyaline. The pathological process involves not only the cartilage and the underlying bone and synovial tissue, but also all the intra-articular and periarticular structures [17, 18, 19]. The biological effect of laser radiation is associated with the following major effects: thermal (predominantly increases the temperature of the liquids, which leads to changes in the phase condition and intracellular pressure); mechanical (result of mechanical changes, kinetic and ultrasonic); electrical (induces changes in the structure of the molecules in the membrane and changes its permeability); photochemical (stimulation of photochemical reactions and selective absorption of the laser radiation of some chemicals in the cell. Bio stimulating (laser radiation supplies quantum energy to the cell without histological changes, i.e., without disruptive action). In this case, the cell uses the resulting energy for its own metabolism [20]. High intensity lasers have also thermal and mechanical effect and induce electromagnetic field, photoelectric, electrochemical, and other changes in the exposed tissues. Advantage of high intensity laser radiation in comparison with low intensity laser radiation is that with increasing the power the depth of penetration is increased, thus the effects in the deep structures, despite the retrogression of quantity and quality (coherence, polarization) of light electromagnetic energy. Pain relieving effect is realized by “Gate Control System” and a result of the stimulating effect of irradiation on regeneration of nerve fibers. The anti-inflammatory effect is realized by modulating the components of the inflammatory reaction, exudation, alteration, and proliferation, and also by stimulating the readapted reactions of the organism. It is realized by blocking cyclooxygenases and lipoxygenases and impact on prostaglandin and prostacyclin synthesis. Cellular bio stimulation is realized through accelerated cellular metabolism by increasing the mitotic index of the cells, which activate the reparative process. Extracellular ion transport is boosted by activating cell exchange. All of these mechanisms lead to beneficial effects regarding edema and stimulation of the healing process, trophycs, and venous and lymphatic microcirculation [21, 22]. According to the findings of our study, the control group receiving quadriceps strengthening exercise (open chain progression isometric type) in addition to calf and hamstring muscles groups stretching. A significant statistical difference in pain level was identified before and after knee exercise with $p = 0.004$.This is following the results of research by Marlina (2015) and Marlina, et al., (2019). which confirmed that knee exercises were effective to reduce knee pain among patients with knee osteoarthritis. Regular knee exercise promotes blood circulation and metabolism in the patella region. Increasing metabolism in the knee resulting improved joint fluids diffusion which helps the supply of adequate nutrients to the cartilage. Adequate nutrients in the joint cartilage relieve the pain experienced by the elderly and also inhibit joint cartilage breakdown [23, 24]. Similar results were reported by Firmansyah & Supayitno (2018).

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Knee exercises reduce pain in the elderly with osteoarthritis [25]. A systematic review conducted by Fransen, et al., (2015) reports that among 44 experiments, exercise significantly relieving pain. Pressure on the cartilage as a result of the exercise force water toward out of the matrix into the synovial cavity. At the occurrence of movement, lubricate prevent friction between bones and reduce pain [26].

The patients treated with HILT, quadriceps strengthening exercise (open chain progression isometric type) in addition to calf and hamstring muscles groups stretching showed a great and statistically significant reduction in pain, improving of function and reduction of effusion. Therefore, HILT demonstrates to have a very good and quick analgesic effect in patients with knee osteoarthritis.

Conclusion

Based on the results of our pilot study we may conclude that high intensity laser therapy could be recommended as a treatment of choice for reduction of pain, improving of function and reduction of effusion in patients with osteoarthritis of the knee. Further studies are needed to clarify the best treatment protocol and the long-term results.

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