The Comparison Of The Low-Level Laser Therapy And High Intensity Laser Therapy On Pain And Functional Ability In Knee Osteoarthritis

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Abstract

Introduction: *Osteoarthritis (OA) of the knee causes disability due to pain and will affect the functional ability to walk. Low-Level Laser Therapy (LLLT) has been shown to reduce pain in knee OA, while High Intensity Laser Therapy (HILT) is able to reach deeper joint areas.*
Method: *This study aimed to compare the effect differences between LLLT and HILT on pain and functional capacity in knee OA. Methods: This is a double-blind randomized controlled trial with 61 subjects randomized into LLLT (n=31) and HILT (n=30) groups. All the subjects were knee OA patient with Visual Analog Scale (VAS) ≥ 4. The laser therapy and exercise were given 3 times per week for 6 sessions. The pain scale evaluated using VAS and functional ability evaluated using 50-feet walk test.*
Result: *After 6 sessions, both LLLT and HILT group showed reduced VAS score [ΔVAS Score LLLT = 3 (2 – 4), HILT = 3 (2 – 5)] and increased walking speed (Δ walking speed for LLLT = 0.23 (0.02 – 1.24) m/s, HILT = 0.22 (0.08 – 0.7) m/s) which were statistically ($p < 0.001$) and clinically significant. HILT group had faster walking speed and greater VAS reduction compared to LLLT group ($p < 0.001$), but there was no significant difference in walking speed between two groups ($p=0.655$).*
Conclusion: *HILT and LLLT combined with exercise were effective in reducing pain and increasing functional ability in knee OA after 6 sessions of intervention. Pain and functional ability improvement was faster and greater in HILT group than LLLT group.*

Keywords: *Knee Osteoarthritis, Low Level Laser Therapy, High Intensity Laser Therapy, LLLT, HILT, VAS, 50-Feet Walk Test*

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Perbandingan Terapi Laser Tingkat Rendah Dan Terapi Laser Intensitas Tinggi Terhadap Nyeri Dan Kemampuan Fungsional Pada Osteoarthritis Lutut

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Abstrak

Pendahuluan: *Osteoarthritis (OA) lutut menyebabkan kecacatan akibat nyeri dan mempengaruhi kemampuan fungsional untuk berjalan. Terapi Laser Tingkat Rendah (LLLT) telah terbukti mengurangi rasa sakit pada OA lutut, sedangkan Terapi Laser Intensitas Tinggi (HILT) mampu menjangkau area sendi yang lebih dalam. Penelitian ini bertujuan untuk membandingkan perbedaan efek LLLT dan HILT terhadap nyeri dan kapasitas fungsional pada OA lutut.*
Metode: *Uji coba terkontrol acak tersamar ganda dengan 61 subjek yang diacak ke dalam kelompok LLLT (n=31) dan HILT (n=30). Semua subjek adalah pasien OA lutut dengan Visual Analog Scale (VAS) 4. Terapi laser dan latihan diberikan 3 kali seminggu selama 6 sesi. Skala nyeri dievaluasi menggunakan VAS dan kemampuan fungsional dievaluasi menggunakan uji jalan 50 kaki.*
Hasil: *Setelah 6 sesi, baik kelompok LLLT maupun HILT menunjukkan penurunan skor VAS [ΔVAS Score LLLT = 3 (2–4), HILT = 3 (2–5)] dan peningkatan kecepatan berjalan (Δ kecepatan berjalan untuk LLLT = 0,23 (0,02–1,24) m/s, HILT = 0,22 (0,08–0,7) m/s) yang secara statistik (p <0,001) dan signifikan secara klinis. Kelompok HILT memiliki kecepatan berjalan yang lebih cepat dan penurunan VAS yang lebih besar dibandingkan dengan kelompok LLLT (p <0,001), namunm tidak ada perbedaan kecepatan berjalan yang signifikan antara kedua kelompok (p=0,655).*
Kesimpulan: *HILT dan LLLT yang dikombinasikan dengan olahraga efektif dalam mengurangi nyeri dan meningkatkan kemampuan fungsional pada OA lutut setelah 6 sesi intervensi. Peningkatan nyeri dan kemampuan fungsional lebih cepat dan lebih besar pada kelompok HILT daripada kelompok LLLT.*

Kata Kunci: *Osteoartiritis lutut, Terapi laser tingkat rendah, Terapi laser tingkat tinggi, LLLT, HILT, VAS, Uji jalan 50 kaki*

Introduction

Knee Osteoarthritis (OA) is the type of OA with the highest prevalence rate, both radiologically and symptomatically. Knee osteoarthritis is a major cause of disability that has social and public health impacts. Patients with knee osteoarthritis often have complaints of pain and decreased functional ability. Pain is the main symptom of knee OA and a major determinant of disability and functional impairment in patients with knee OA.[1–3]

In several studies, low-level laser therapy (LLLT) has been shown to significantly reduce acute and chronic pain in various conditions, including knee osteoarthritis. However, in recent times, high-intensity laser therapy (HILT) has been introduced into the realm of physical medicine. The advantage of HILT over LLLT is the ability of HILT to reach and stimulate large and/or deep joints that are difficult to reach by low-intensity laser therapy.[4,5]

HILT has special characteristics in produce a photomechanical effect on the treated tissue, due to the high duration and intensity of the laser beam impulses delivered. This phenomenon can produce important therapeutic effects because it can trigger biological signals to stimulate tissue repair and regeneration, along with activation of the vascular and lymphatic systems.[6–10]

Low-Level Laser Therapy (LLLT) or also known as low-intensity laser is defined as a laser with a sufficiently low energy output that it does not cause an increase in the temperature of the treated tissue exceeding

36.5°C. It can either inhibit or stimulate cellular activity through the regulation of metabolism and cell proliferation.[11]

This study aims to compare the difference effect between LLLT and HILT on pain and functional ability in knee OA patients for six sessions of therapy in Cipto Mangunkusumo National General Hospital, Jakarta, Indonesia.

Methods

This study is a double-blind randomized controlled clinical trial to examine the differences in the effectiveness of LLLT and HILT on pain scale and functional ability in knee OA patients. This research was conducted at Department of Medical Rehabilitation, Cipto Mangunkusumo National General Hospital from February to April 2018.

The sample size was 40 subjects divided into two groups that consist of 20 subjects for each group. The inclusion criteria were patients diagnosed with knee OA according to the American College of Rheumatology (ACR) with visual analog scale (VAS) score ≥ 4 for both knees, able to ambulate for 15 meters, and willing to participate in this study by signing the informed consent.

Subjects will be randomized into two groups with a single blind randomized technique divided into 2 groups consist of group I who received LLLT and group II who received HILT. Subjects were given therapy according to their group with a frequency of 3 times a week for 2 weeks with total 6 sessions. The exercise consisted of quadriceps setting exercise, hamstring setting exercise and straight leg raise exercise performed every day for 3 times a day, consisting of 3 sets of exercises with 10 repetitions each set with resting for 2 minutes between sets. The duration of muscle contraction was hold for 10 seconds and rest for 5 seconds.

Figure 1. Therapeutic Area of Low- Level Laser Therapy

Group I received LLLT with a GaAs BTL-5110 diode laser with a wavelength of 830 nm and an output power of 400mW. A dose of 10 J/cm^2 was given to the medial and lateral knee joint space with a total dose of 60 J per treatment (Figure 1).

Group II received HILT with a BTL-6000 diode laser with a wavelength of 1064 nm and an output power of 12 Watts using a probe with a 3 mm spacer. The patient is positioned supine and the knee is flexed 30° and the laser probe is placed perpendicular to the treatment area such as the medial and lateral knee joints. This therapy has 2 phases consist of phase I (analgesia phase) and phase II (bio-stimulation phase).

Phase I is carried out with continuous circular motions for 2 minutes according to the L-7129 program, with a power of 10 Watts, pulse application with a frequency of 25 Hz, a dose of 12 J/cm^2, a total energy of 300 J, a wavelength of 1064 nm, a therapeutic area of 25 cm^2. Phase II was carried out with continuous linear motion for 4 minutes according to the L-7130 program, with a power of 5 Watt, a dose of 120 J/cm^2, a total energy of 300 J, a wavelength of 1064 nm, a therapeutic area of 25 cm^2, with a duration of 4 minutes with a power 5 Watts (Figure 2).

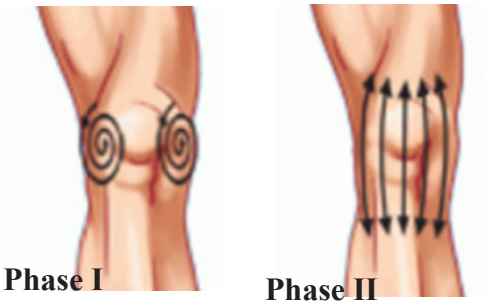

Figure 2. Laser Application Pattern in Phase I and II

The evaluation was measured every session of therapy included the measurement of pain scale using VAS and functional ability using 50-feet walk test for both groups. The data will be analysed using SPSS 23 version for comparison the difference of each session of each group, before and after therapy of each group, and effect difference between two groups of intervention.

Result

The number of subjects who participated in this study was 61 subjects (Table 1), exceeding the minimum sample calculations of 40 subjects. Randomization was conducted to divide the subjects into 2 groups, namely 31 subjects in group I and 30 subjects in group

II. There were no drop outs in this study. The mean age in group I was 59.55 years while 61.93 years in group II. The age of the subjects in both groups was dominated by the age group of 50-60 years, as many as 80.6% in group I and 73.3% in group II. In both groups, the subjects in this study were mostly housewives, 48.4% in group I and 50% in group II. The severity of knee osteoarthritis with the Kellgren-Lawrence classification in both groups was dominated by grade III, 70% in group I and 63.3% in group II. All the subjects

Table 1. Subject Characteristics

Subject Characteristics	Group I (n=31)	Group II (n=30)	p-Value
	n (%)	n (%)	
Age (years)	59.55 ± 7.22	61.93 ± 7.15	0.200a
Age Category			
< 50 years	4 (12.9)	2 (6.7)	
50 - 60 years	25 (80.6)	22 (73.3)	0.241b
> 60 years	2 (6.5)	6 (20)	
Gender			
Male	3 (9.7)	1 (3.3)	0.612c
Female	28 (90.3)	29 (96.7)	
BMI (kg/m2)	26.91 ± 3.43	26.89 ± 4.45	0.984a
BMI Category			
Underweight	0 (0)	1 (3.3)	
Normal	5 (16.1)	5 (16.7)	
Overweight	4 (12.9)	3 (10.0)	0.885b
Obesity I	17 (54.8)	16 (53.3)	
Obesity II	5 (16.1)	5 (16.7)	
Educational Background			
Pimary – junior High School	4 (12.9)	6 (20)	
Senior High School	12 (38.7)	11 (36.7)	0.885b
Diploma	10 (32.3)	8 (26.7)	
Bachelor - Doctoral	5 (16.1)	5 (16.7)	
Occupation			
Housewives	15 (48.4)	15 (50)	
Retired	11 (35.5)	8 (26.7)	0.673b
Employee	5 (16.1)	7 (23.3)	
Knee OA Degrees			
II	9 (29)	11 (36.7)	0.525b
III	22 (71)	19 (63.3)	
Initial VAS (cm)	6 (4 – 7)	6 (4 – 7)	0.881d
15-meter walk test			
Travel time (second)	14.52 (7.45 – 22.81)	16.78 (10.19 – 56.27)	0.030d*
walk speed (meters/second)	1.03 (0.66 – 2.01)	0.89 (0.27 – 1.47)	0.030d*

[a]Wilcoxon Test [b]Mann-Whitney Test [*]statistically significant, p<0.05

the gender was dominated by women by 90.3% in group I and 96.7% in group II. The nutritional status in both groups was dominated by obesity grade I by 54.8% in group 1 and 53.3% in group II. The education background in both groups was dominated by the high school level which was 38.7% in group I and 36.7% in group II. The occupations of in both groups had experienced knee pain for more than 1 year.

In both groups, the median value of VAS was 6 with a range of 4-7 before intervention. There was a statistically significant improvement of VAS in every session of therapy of both groups (Table 2). Table 3 and Figure 3 showed that the improvement of VAS

Table 2. The Difference of Visual Analog Scale (VAS) Before and After Intervention

VAS	Group I	p-value	Group II	p-value
	Median (Min-Max)		Median (Min-Max)	
Before therapy	6 (4 – 7)		6 (4 – 7)	
After 1st therapy	5 (3 – 7)	0.025*	5 (3 – 7)	<0,001*
After 2nd therapy	4 (2 – 6)	<0,001*	4 (2 – 6)	<0,001*
After 3rd therapy	3 (2 – 5)	<0,001*	3.5 (2 – 5)	<0,001*
After 4th therapy	3 (1 – 5)	<0,001*	3 (1 – 5)	<0,001*
After 5th therapy	2 (1 – 4)	<0,001*	2 (1 – 4)	<0,001*
After 6th therapy	2 (1 – 4)	<0,001*	2 (1 – 4)	<0,001*

Wilcoxon test * statistically significant, p<0.05

Table 3. The Comparison of VAS Difference Between Group I and Group II

VAS	Group I	Group II	p-value
Before therapy	6 (4 – 7)	6 (4 – 7)	0.881
After 1st therapy	6 (4 – 7)	5 (3 – 7)	0.012*
After 2nd therapy	5 (3 – 6)	4 (2 – 6)	0.031*
After 3rd therapy	5 (3 – 6)	3,5 (2 – 5)	<0.001*
After 4th therapy	4 (3 – 6)	3 (1 – 5)	0.001*
After 5th therapy	3 (2 – 5)	2 (1 – 4)	0.003*
After 6th therapy	3 (1 – 4)	2 (1 – 4)	0.032*
Difference VAS initial-final	3 (2 – 4)	3 (2 – 5)	0.026*

Mann-Whitney Test * statistically significant, p<0.05

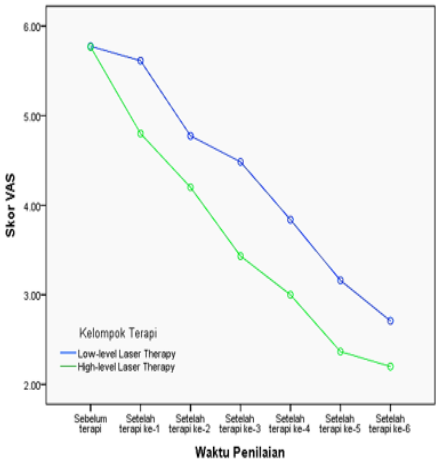

Figure 3. The Comparison of the Rate of Change in Knee Pain Degrees Between Two Groups

difference in group 2 was better than group 1 and significantly difference(p<0.001).

Table 4 showed the improvement of walking speed before and after therapy that is significantly difference for each group. The walking speed improvement was better in group II than group I but not significantly difference (p>0.05).

Discussion

In this study, all subjects had bilateral knee OA. Both knees were treated with laser therapy, but the knee being evaluated was the knee with the higher VAS score. In this study, all the subjects were able to walk without a walker. Although in daily life the patient carries a walk aid such as a single cane, however, the subject can perform a 15-meter walk test without a walker.

This study showed that there was an improvement of pain intensity that is statistically and clinically significant in the group receiving the LLLT intervention. A statistically significant improvement was obtained since the first treatment which was a decrease in the VAS score of 16.67% compare to VAS score before intervention by 1 point. Based on the study by Tubach et al (2005), it is known that the Minimal Clinically Important Improvement (MCII) for the VAS score in knee OA is > 19.9 mm.[12] Therefore, the decrease in VAS scores after the first treatment was not clinically significant. In this study, there was a clinically significant change in VAS score after the third treatment, which was a decrease in VAS score by 40% from VAS before treatment by 2 points.

After 6 sessions of intervention, the VAS score was decrease as many as 50% (42.86± 80%) from the initial VAS score. The difference in VAS scores before and after therapy ranged from 2 to 4 points, with a median value of 3. The results obtained in this study are in line with the theory of LLLT role in reducing pain level of knee OA. The LLLT produces an analgesic effect by altering nerve transmission or inhibiting sensory nerve activity to increase the pain threshold and increase the production of endorphins.

Table 4. The Walking Speed Comparison of 15-Meter Walk Test Between Group I and Group II

Median (Min – Max) Walking Speed (Second/ Meter)			p-value
	Group I	Group II	
Before Therapy	1.03 (0.66 – 2.01)	0.89 (0.27 – 1.47)	0.03b*
After Therapy	1.27 (0.67 – 2.48)	1.18 (0.43 – 2.07)	0.151b
p-value	<0.001a*	<0.001 a*	
The difference	0.23 (0.02 – 1.24)	0.22 (0.08 – 0.7)	0.655b
Difference Percentage	19.74 (1.94 – 120.91)	27.67 (10.14 – 86.25)	0.126b

*[a]Wilcoxon Test [b]Mann-Whitney Test * statistically significant, p<0.05*

Laser irradiation also reduces pain by reducing swelling, increasing tissue oxygenation, improves microcirculation, activates angiogenesis, stimulates immunological processes and nerve regeneration. LLLT is presumed to increase joint cartilage regeneration through chondrocyte proliferation and increase extracellular matrix synthesis and secretion.[13–16]

This study also in line with the results from several previous studies. Alghadir et al conducted a single-blind randomized clinical trial to investigate the effect of LLLT on reducing pain and functional ability in chronic knee OA patients and found that there was a 47.26% and 40.39% reduction in pain at rest and activity after 8 sessions of LLLT therapy, respectively.[17]

Alfredo et al investigated the effect of LLLT in combination with exercise therapy. Clinically and statistically significant pain improvement results were obtained in the group that received LLLT intervention and exercise therapy.[18]

Youssef et al conducted a study that compared the effects of a combined exercise program with the administration of low-level laser therapy with two different doses compared to the exercise program alone as a placebo group. It was reported that there was a significant decrease in VAS scores in the three treatment groups, with the best results obtained in the group receiving a combination of exercise programs and low-level laser therapy at a dose of 6 J/cm², followed by a dose of 3 J/cm² and the lowest results were obtained in the placebo group.[17,18]

The results of this study showed that there was a decrease in the VAS score up to 83.33% from the initial VAS score after 6 times of HILT therapy. The results of a statistically significant decrease in VAS scores in the HILT group were obtained from the first treatment and were followed by a further decrease in VAS scores until the last treatment. Compared with the VAS score before treatment, the VAS score decreased by 25% or 1 point after the first treatment.

A clinically significant change in the VAS score was obtained after the second HILT therapy and exceeded the MCII VAS score (>19.9mm). The VAS score down up to 2 points or 20 % of the initial VAS score. After 6 sessions of intervention, the VAS score decrease up to 66.67% of the initial VAS score with the median value was 3 (2±5). The result of this study was in line with the theory that stated HILT can reduce pain through its anti-inflammatory effect. The optical energy of HILT penetrates the therapeutic area and diffuses into the tissue causing photochemical effects, including mitochondrial oxidation and facilitation of ATP formation which increases metabolism, increasing circulation through vascular, lymphatic vasodilation effects, and analgesic effect on nerve endings. Therefore, fluid accumulation in the form of edema and exudation can be reabsorbed so that it subsides quickly.[8,19–21]

The result of this study are in line with previous study. Study by Stiglic-Rogoznica et al. (2011) showed that the effect of HILT on pain in knee OA patients for 10 consecutive days with a session duration of 20 minutes. The average initial VAS was 57 mm (45-70 mm) and the average VAS post intervention was 22 mm (10 -30 mm). The results showed a decrease in VAS of 20 to 50 mm with a percentage decrease in VAS score of 63±25% which was clinically (MCID > 19 mm) and statistically (p<0.001) significant.[8]

Angelova and Ilieva (2016)[6] conducted a single-blind randomized controlled clinical trial of the effects of HILT in knee OA patients. HILT was administered using a 1064

nm NdYAG semiconductive laser, 12 W output power, a total dose of 300 J for the analgesia phase and 3000 J for the biostimulation phase. HILT therapy was given every day for 7 days for a total of 7 times. In this study, there was a significant reduction in the degree of pain after 7 sessions of HILT therapy, reaching more than 80% of the VAS score before treatment, which was able to be maintained for 1 and 3 months after therapy.[6]

In this study, the LLLT and HILT groups experienced a VAS difference with a median value of 3, but the HILT group had a wider improvement of VAS delta with a range of 2 – 5 points, while the LLLT group had an improvement of VAS delta range of 2 – 4 points. In the LLLT group, the percentage decrease in VAS reached 80% compared to the initial VAS, while in the HILT group greater decrease, reaching 83.33%.

The results obtained in this study are in line with the results of previous studies. Kheshie et al (2014)[22] conducted a randomized controlled clinical trial comparing the effects of LLLT and HILT in knee OA patients. The study subjects had knee pain duration of more than 6 months and knee OA grades 2 and 3 according to the Kellgren-Lawrence classification. Subjects were randomized into 3 groups, each receiving HILT, LLLT and placebo laser 2 times a week for 6 weeks for a total of 12 treatments. All the subjects were given the same exercise program. The study found that the combination of LLLT nor HILT therapy and exercise was superior in reducing pain compared to exercise and placebo lasers. Further analysis showed that the combination of HILT and exercise was more effective in reducing pain than the combination of LLLT and exercise.[22]

Gworys et al[23] compared the effects of HILT, LLLT and placebo lasers. Subjects were divided into 4 groups, spesifically group I who received LLLT with a wavelength of 810 nm, dose 8 J/point, density 12.7 J/cm^2, output 400mW; group II received HILT with a combination of wavelengths 808 nm and 905 nm, output 1100 mW, dose 12.4 J/point, density 6.21 J/cm^2; Group III received HILT at a dose of 6.6 J/point, density 3.28 J/cm^2, and group IV received placebo laser therapy. The results of the improvement in the VAS score were statistically significant in groups I, II and III. The greatest improvement in VAS scores was found in group II, while in groups I and III the results were equivalent.

The advantage of using HILT over LLLT is the safe use of a high power laser with a specific wavelength of 1064 nm which is a very short time and low duty cycle that can generate enormous energy and penetrate the target tissues with a low risk of tissue damage. By gradually increasing the density and decreasing the laser frequency, HILT can reach deeper tissues with photothermal, photochemical and photomechanical effects that stimulate tissue response.[24]

This study found that there was a statistically significant improvement in the results of the 15-meter walk test in both groups after intervention. The improvement in walking speed before and after therapy were 0.23 meters/second in the LLLT group and 0.22 meters/second in the HILT group. There was no statistically significant difference in walking speed between two groups. The improvement of walking speed after intervention of both group was clinically significant MCII value (> 0.10 m/s)[25] and statistically significant with $p<0.001$.

This is in line with the results of a study conducted by Kola and Kola (2012)[26] which compared the effectiveness of LLLT and HILT in subjects with knee OA. Subjects were divided into 3 groups, namely group I received LLLT at a dose of 1.8 J/cm^2 at 4 points, while group II received HILT at a dose of 3.6 J/cm^2, and group III received placebo laser therapy. The results of ga decrease in VAS scores and an increase in functional ability in both groups that received LLLT and HILT with the largest changes were found in the HILT group. This study concluded that the greater the reduction in pain, the greater the functional ability to walk, which was obtained by administering HILT.

The improvement of functional ability was mainly due to the reduction in the degree of pain with the administration of LLLT and HILT therapy. The reduced degree of pain experienced also makes the patient able to perform the programmed home exercises, so that the combination of laser therapy and exercise will have a synergistic effect on the functional ability of the knee, in this case the ability to walk. With the improvement of pain and ability to walk, the subject will generally experience an increase in the quality of life.

Side effects that can arise from laser therapy are generally mild and do not require special treatment, including mild allergic manifestations on the skin, numbness, rash and warmth in the laser therapy area.[27] In this study, there were no side effects due to LLLT or HILT therapy. In general, laser therapy does not cause side effects when carried out

according to the protocol by a trained doctor, so there are rarely reports of side effects.

There are several limitations in this study. The first limitation is that there is no objective assessment in this study such as an objective assessment of the degree of pain using a dolorimeter or an ultrasound examination of the knee joint to determine the effect of HILT on changes in the degree of tissue inflammation in the knee joint. The second is that there is no long-term follow-up so that there is no data on the long-term effect of HILT and it is not known how long the effects of reducing pain and increasing functional ability can be maintained. The third limitation is the absence of a control group who did not receive laser therapy/received placebo laser therapy. However, this study was the first double-blind randomized controlled clinical trial to compare the effects of HILT and LLLT on knee OA in Indonesia.

Conclusion

There was a statistically and clinically significant effect of laser physical therapy on the degree of pain and functional ability of patients with knee OA. HILT was superior in greater VAS score and walking speed improvement compared to LLLT but not statistically difference between the two groups. The LLLT and HILT both provided a statistically and clinically significant improvement in pain and functional ability improvement of knee OA patients The authors suggest that further study should be carried out with an objective assessment of the knee pain intenstity and degree of inflammation in the knee joint structure, and also further study with long-term follow-up to evaluate the effects of LLLT and HILT and to know how long the pain-reducing effect can be maintained.

Conflicts of Interest

The Authors declare that there is no conflict of interest.

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