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Effect of High-Power Laser Therapy Versus Shock Wave Therapy on Pain and Function in Knee Osteoarthritis Patients: A Randomized Controlled Trial

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Abstract

Objective: The aim of this study was to evaluate and compare the effects of extracorporeal shock wave therapy (ESWT) and high-intensity laser therapy (HILT), as outpatient physical therapy modalities, on knee osteoarthritis (KOA) patients.
Materials and methods: The treatment program was completed by 40 individuals with stage II KOA (according to Kellgren and Lawrence) who were randomly allocated to one of two groups. They have had more than grade 3 pain on the visual analog scale (VAS) during activities for the last 3 months, with body–mass index less than 30 and no history of knee operation, fracture, cancer, or other neuromuscular or musculoskeletal diseases that may affect study results. The ESWT group ($n=20$, mean age $=40.12 \pm 9.45$ years) received ESWT, 0.05 mJ/mm^2, one session/week for 4 weeks, and the HILT group ($n=20$, mean age $=46.62 \pm 8.68$ years) received HILT, 1500 mJ/cm^2 in each session, three sessions/week for 4 weeks. Both groups received conservative physical therapy programs. Before and after 4 weeks of intervention, pain, physical function, and disability were assessed using a VAS, 6-min walking test, and the Western Ontario and McMaster Universities Osteoarthritis Index.
Results: When the pre- and post-treatment mean values of dependent variables of both groups were compared, there were statistically significant improvements in both groups. Significant differences in the measured variables were also discovered in favor of the HILT group compared with the ESWT group.
Conclusions: HILT showed a superior effect compared with ESWT on pain, physical function, and disability in chronic KOA patients.
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Keywords: knee osteoarthritis, shock waves, high-intensity laser, pain

Introduction

Knee osteoarthritis (KOA) is a complicated degenerative change in the biomechanical characteristics of articular cartilage, subchondral tissues, and bone. Pain, disability, and physical dysfunction are all symptoms of osteoarthritis (OA).[1] Age, genetics, and biomechanical and metabolic factors, such as obesity, could increase the risk of KOA.[2,3] KOA signs and symptoms worsen over time with associated decline in the subject's functional abilities.[4] The global incidence of KOA is about 29% in those over the age of 40, with women having greater prevalence (21.7%) than men (11.9%).[5]

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Several physical therapy methods are available to treat KOA, including low-level laser, high-intensity laser therapy, ultrasound, water exercises, transcutaneous electrical nerve stimulation, therapeutic exercises, education, weight loss, kinesio taping, and social support, among others.[6–8] Despite the availability of various treatment options for KOA, pain and functional impairment commonly remain.[9] As a result, more research into novel treatments for KOA is needed.

Extracorporeal shock wave therapy (ESWT) is now used to treat a wide range of musculoskeletal conditions, including Achilles tendinopathy, calcaneal spur, plantar fasciitis, patellar tendinopathy, calcific tendinitis of the shoulder, epicondylitis, and nonunion and delayed union of long bone fracture.[10] In animals, ESWT may delay OA development, enhance function, and suppress chondroprotective actions.[11,12] Many studies have found that ESWT reduces pain and improves knee function in those with KOA while having no significant side effects.[13–19]

High-intensity laser therapy (HILT) is recognized as a relatively new, safe, painless, effective, noninvasive treatment option for patients with KOA.[20–25] HIL therapy, especially with the neodymium-doped yttrium aluminum garnet (Nd:YAG) laser, stimulates deeper tissues with greater power than low-level laser therapy.[25] HILT, with its special photothermal, photomechanical, and photochemical effects, produces analgesia, antiedema, and biostimulating actions and other therapeutic advantages for KOA patients.[22,26]

In addition, HILT has been used with different disorders such as KOA,[24,27] subacromial impingement syndrome,[28] frozen shoulder,[29] chronic back pain,[25] osteoporosis,[30,31] and postburn pruritus.[32]

Some research tested the effectiveness of ESWT or HILT in treating patients with KOA separately, but to our knowledge, no controlled randomized research directly compared the efficacy of both modalities. This study aimed to compare the effectiveness of ESWT and HILT on pain and function in patients with KOA.

Materials and Methods

Design

This study design is a parallel, randomized active-controlled trial. Patients and clinical examiners were blinded to the study hypothesis. The procedures followed agreed with the Institutional Ethics Committee Clearance, and written informed consent was taken.

Participants

Forty patients of both sexes (20 males and 20 females), age ranging between 40 and 55 years, diagnosed with chronic KOA according to the American College of Rheumatology criteria were recruited from patients who visited the outpatient clinic of Cleopatra Hospital between December 2020 and May 2021.

The study included patients who had stage II KOA measured by X-ray, according to Kellgren and Lawrence, knee pain more than 3 on the visual analog scale (VAS) during daily activities in the last 3 months, body–mass index (BMI) less than 30, and willingness to participate and be committed to our treatment program in the next month. Patients were excluded from the trial if they had a knee deformity, rheumatoid arthritis, a history of knee surgery, bone implants, a fracture, cancer, neuromuscular illness, or any other ailment that may impact the study's outcomes. Patients were also eliminated if they had had knee or lower limb trauma, injury, or a knee intra-articular injection in the previous 6 months or were presently involved in sports or another physical therapy program.

Randomization

Each patient signed a written informed consent form after being told about the nature, purpose, and advantages of the study, their right to decline or withdraw from the study at any time, and the confidentiality of any information gathered. Anonymity was assured through the coding of all data.

After the clinical assessment and establishment of diagnosis by a physician, a physical therapist, blinded to the study hypothesis, allocated patients to one of the study groups (ESWT group or HILT group) through opening sealed randomization block envelopes (blocks of six stratified by gender). He also scheduled patients to treatment sessions. A blinded, independent research assistant prepared randomization blocks.

Intervention protocols

Treatment sessions were conducted at the physical therapy outpatient clinic in Cleopatra Hospital. A different therapist applied each modality; three different physical therapists applied the three interventions. How the therapists applied the treatment was blinded to group allocation.

Another therapist not aware of group allocation tested the participants at baseline and after the final sessions (after 4 weeks of treatment) in both groups.

ESWT protocol.

Patients in the ESWT group received 1000 extracorporeal shock wave pulses (Evotron RFL0300 Focal Shockwave; manufactured by Swiss Tech Medical AG, Switzerland) with an intensity of $0.05\,mJ/mm^2$, one session/week for 4 weeks. ESWT is applied to the tender point of the medial tibial plateau area in the affected knee while the patient is lying in a supine position with knees bent at 90°. Following each session, the therapist instructed the participants to refrain from engaging in physical activity such as running or carrying heavy things for 48 h.[15]

High-intensity pulsed Nd:YAG laser therapy protocol.

Participants in the HILT group received high-intensity pulsed Nd:YAG laser therapy through the HIRO 03 device (ASA, Arcugnano, Vicenza, Italy) at a frequency of 30 Hz and total delivered energy of $1500\,mJ/cm^2$ in each session, three sessions/week for 4 weeks. The delivered energy was automatically calculated by the HIRO 03 HILT machine. To expose the joint surfaces to the laser beam, the HILT handpiece was positioned in contact with and perpendicular to the medial side of the knee while the patient lay supine with the knee flexed at 30° (optical windows). The HILT handpiece was then moved transversely and longitudinally in the anterior, medial, and lateral aspects of the knee joint, emphasizing the joint line between the tibial and femoral epicondyles.[24,27]

Conditional physical therapy treatment protocol. The conservative physical therapy (CPT) regimen was likewise given to all participants in both groups. It consisted of three 10-sec sets of isometric exercises for the quadriceps, hamstrings, and hip abductors. Each set consisted of 20 repetitions. They were also given a 15-min hot water fomentation treatment. The therapist gave each patient an exercise sheet and told them to do the exercises as a home program when they did not go to the clinic, doing three sets of 20 repetitions twice a day. The therapist requested patients to record the frequency and repetition of each exercise to measure adherence.[33,34]

Outcome measures

Pain assessment. Using a 10-cm VAS, the tester assessed the level of discomfort. It is a 0 to 10 scale for measuring pain, with 0 indicating no pain and 10 reflecting the worst possible suffering. Using the VAS, patients were asked to indicate where on the scale they felt the most discomfort in the last month.[35]

Six-minute walking test. The 6-min walking test (DW6m) determines how far a patient can walk on a solid level surface in 6 min. In healthy older persons, those who have had knee or hip arthroplasty, and those with OA, fibromyalgia, and scleroderma, it is an accurate and valid physical and functional assessment tool.[36]

Western Ontario and McMaster Universities Osteoarthritis Index. The Arabic version of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was used to measure functional disability. WOMAC is an OA subscale developed by researchers from Western Ontario and McMaster Universities. With 24 questions, it is a verified, disease-specific self-reporting survey. More severe functional impairment is indicated by higher scores[37] (Fig. 1).

Sample size calculation

Preliminary power analysis was performed using G*Power 3.1.9.2 software to prevent a type II error with the following parameters: power ($1-\alpha$ error P) = 0.95, $\alpha = 0.05$, and effect size = 1.187. Analysis was determined as a sample size of 40 individuals divided into two groups (20 each). For the sake of this calculation, we used pain intensity as the main outcome measure in a 12-subject pilot research.

Data analysis

Our primary analysis was conducted using an intent-to-treat approach and therefore included all randomized patients. No subjects dropped out of the study after randomization (Fig. 1).

SPSS for Windows, version 20, was utilized (Chicago, IL). To compare the clinical effects of ESWT and HILT modalities, a statistical analysis was conducted to compare results of pain, DW6m, and overall WOMAC scores for KOA patients in both groups. The Kolmogorov–Smirnov test was applied to confirm data normality before the final analysis. Descriptive statistics (mean and standard deviation) were computed for all the data collected. A 2×2 mixed design multivariate analysis of variance (MANOVA) was used in two types of comparisons: between-group comparisons and within-group comparisons of each dependent variable's examined factors of interest. Two independent variables were used in the test. One of the factors with two levels was the tested group; between the subject and the subject factor (laser group and traditional treatment group). Two measurement periods made up the second component, which had two levels of a topic (before and after treatment). To determine statistical significance, 0.05 was determined.

Results

A total of 40 patients were randomly allocated to one of two groups (ESWT group or HILT group) (Fig. 1). The ESWT group consisted of 20 KOA patients, 9 men and 11

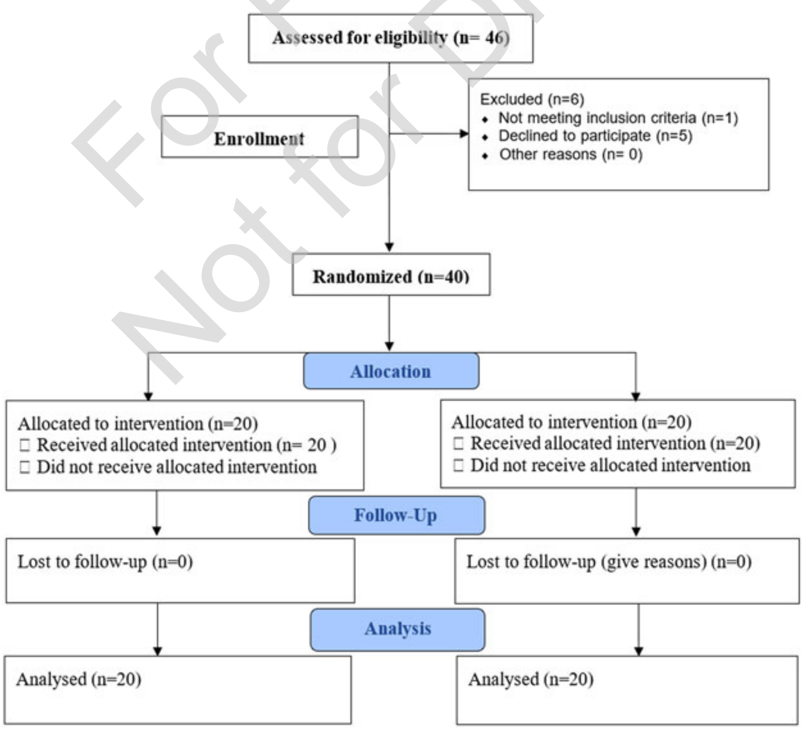

FIG. 1. Flow chart of the participants.

Table 1. Participants' Characteristics (Mean ± Standard Deviation) at Baseline

	ESWT (mean ± SD)	HILT (mean ± SD)	p
Age (years)	40.12 ± 9.45	46.62 ± 8.68	0.81
Weight (kg)	76.02 ± 10.23	77.17 ± 6.38	0.82
Height (cm)	162.2 ± 7.1	163.2 ± 7.3	0.11
BMI (kg/m^2)	28.82 ± 5.23	29.26 ± 2.48	11.09
Pain duration (days)	17.2 ± 11.6	18.7 ± 13.3	0.61

p Value: level of significance.
BMI, body–mass index; ESWT, extracorporeal shock wave therapy; HILT, high-intensity laser therapy; SD, standard deviation.

women, with mean age = 40.12 ± 9.45 years. The HILT group consisted of 20 KOA patients, 10 men and 10 women, with mean age = 46.62 ± 8.68 years.

As shown in Table 1, both groups have similar features at baseline as there were nonsignificant differences between the groups regarding mean values of age, weight, height, BMI, and duration of pain ($p > 0.05$).

The pre- and post-treatment values of the tested dependent variables (VAS, DW6m, and WOMAC scores) were compared within each group. Pairwise comparison (MANOVA post hoc test) revealed a significant improvement in mean values of pain [percentage of improvement with extracorporeal shock wave therapy (ESWT) = 30% and HILT = 53%], distance walked in 6 min (percentage of improvement with ESWT = 9% and HILT = 30%), and total WOMAC (percentage of improvement with ESWT = 39% and HILT = 62%) scores measured in both groups at the end of treatment compared with the corresponding mean values before treatment ($p < 0.05$) (Table 2). There was no statistically significant difference between the two groups at the start regarding the examined dependent variables. After 4 weeks of therapy, the pairwise comparison showed that the HILT group had statistically significant lower mean values of pain and WOMAC scores and higher mean values of DW6m than the ESWT group ($p < 0.05$) (Tables 2 and 3).

Table 2. Pain, DW6m, and Total Western Ontario and McMaster Universities Osteoarthritis Index Scores for Both Groups

Measure	ESWT (mean ± SD)	HILT (mean ± SD)	p^a
Pain intensity			
Preintervention	6.03 ± 1.24	6.55 ± 1.31	>0.05
Postintervention	4.22 ± 1.31	3.20 ± 1.42	<0.05
p^b	0.2051	0.0235	
DW6m			
Preintervention	491.2 ± 132.1	473.7 ± 120.5	>0.05
Postintervention	538.6 ± 132.2	681.2 ± 133.1	<0.05
p^b	0.6641	0.0016	
WOMAC			
Preintervention	53.1 ± 12.1	48.3 ± 13.2	>0.05
Postintervention	32.2 ± 14.05	18.1 ± 11.2	<0.05
p^b	0.2380	0.0012	

[a]Between-group comparison.
[b]Within-group comparison.
DW6m, 6-min walking test; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

Discussion

In this randomized clinical trial, the effectiveness of ESWT and HILT, as electrotherapy modalities, was assessed in the treatment of KOA patients. This trial's findings are novel as no evidence on the effectiveness of ESWT versus HILT in KOA has been reported so far.

Shock waves are sound waves with unique physical properties such as nonlinearity, high peak pressure, followed by low tensile amplitude, a short rising time, and a short duration (10 ms). They feature a single pulse, a broad frequency range (0–20 MHz), and a large pressure amplitude (0–120 MPa). These features result in positive and negative shock wave phases. The positive phase creates direct mechanical forces, but the negative phase causes cavitation and gas bubbles that collapse at high speeds, creating a second wave of shock waves that generate an electrical pulse that promotes cell healing with each magnetic impulse.[38]

Our results showed significant improvement in pain, WOMAC scores, and DW6m after ESWT. These results were in accordance with the study by Zhao et al.[39] who tested the effect of ESWT on 70 KOA patients and found statistically higher improvements in pain and function in KOA patients in 12 weeks with ESWT, compared with placebo. ESWT also improved pain and working in KOA patients, which were confirmed by Kim et al.[40] who reported that low-power ESWT (0.040 mJ/mm^2) was effective in KOA treatment, with better results using medium-power ESWT (0.093 mJ/mm^2).[40] Further, ESWT was an effective treatment in reducing pain and improving function measured by WOMAC scores compared with alendronate nonsteroidal anti-inflammatory drugs in a 12-month follow-up retrospective study on 126 mild to moderate KOA patients with painful bone marrow edema.[17] In another retrospective study on 105 KOA patients, ESWT revealed significant improvement in pain and WOMAC scores compared with low-level laser therapy after 6 and 12 weeks of follow-up after treatment with no detectable side effects.[18] In comparison with kinesiotherapy (KIN), ESWT improved function (decreased WOMAC scores) and increased knee range of motion (ROM) better than KIN in patients with OA of the knee after five weekly interventions.[16] Further, a comparison of ESWT in addition to CPT versus CPT only on 20 degenerative KOA patients showed statistically better results in the ESWT and CPT group for pain and function.[14] In addition, a comparison between intra-articular injection of hyaluronic acid and ESWT showed similar results after 1 and 3 months of follow-up in all measurement variables: VAS, WOMAC score, Lequesne index, 40-m fast-paced walk test, and stair climb test.[15]

In partial agreement with our results, Imamura et al.[41] studied the effect of radial ESWT (rESWT) versus placebo on severe primary KOA patients. The outcome measures included WOMAC score, pain during movement after 3 months, stiffness, and muscle tolerance to pressure. Results showed a significant decrease in the WOMAC pain subscale, with no improvement in other results.[41] The different results may be due to different doses and parameters of ESWT as we focused on ESWT, while Imamura et al. used rESWT. In addition, another difference is the criteria used for patients as we treat only mild and moderate cases, not severe cases.[41]

Table 3. Table to Report Parameters in Experimental and Clinical PBM Articles

Manufacturer	ASA, Arcugnano, Vicenza, Italy
Model identifier	HIRO 3.0
Year produced	2019
Number and type of emitter (laser or LED)	High-intensity pulsed Nd:YAG laser source
Wavelength and bandwidth, (nm)	1064 nm
Pulse mode (CW or Hz, duty cycle)	30-Hz pulse duration: ≤100 μs
Beam spot size at target (cm^2)	1 cm^2
Irradiance at target (mW/cm^2)	1500 mJ/cm^2
If pulsed peak irradiance (mW/cm^2)	
Exposure duration (sec)	≤100 μs
Radiant exposure (J/cm^2)	1500 mJ/cm^2
Radiant energy (J)	
No. of points irradiated	
Area irradiated (cm^2)	Average area size, about 12 cm length and 3 cm width
Application technique	Contact technique
Number and frequency of treatment sessions	three sessions/week for 4 weeks
Total radiant energy over the entire treatment course (J)	4500 mJ/week 4 ×

CW, continuous wave; PBM, photobiomodulation.

There is no specific, precise ESWT mechanism to treat symptoms of KOA. Even so, ESWT was speculated to increase articular cartilage regeneration. Radial extracorporeal shock waves promote the self-renewal of subchondral bone stem/progenitor cells by increasing YAP expression and promoting YAP nuclear translocation.[42] In addition, Zhao et al.[12] suggest that the application of ESWT in KOA rabbits decreases nitric oxide in the synovial cavity of the knee joint. Therefore, the catabolism in the OA joint was reduced.[12] In addition, ESWT revealed significant improvement in subchondral bone repair, as an early sign of OA, in induced osteoarthritis knees (OAK).[43]

Moreover, ESWT can reduce anoxic pain (theory of gate control) and increase the anoxic pain threshold.[44] It can also cause endorphins to be released.[45] It may also reduce substance P in the target and dorsal root ganglion cells and selectively destroy unmyelinated nerve fibers within the ESWT focal region.[46,47]

Results in this study showed improvement of pain and function among patients in the HILT group. The present study findings agreed with the study by Akaltun et al., who compared the effect of HILT and exercise (HILT+ET) with placebo HILT and exercise (PL+ET) on 40 KOA patients. After treatment, VAS and WOMAC scores were significantly lower in the sixth week in the HILT+ET group compared with the PL+ET group, with statistically significant increases in active knee flexion and femur cartilage thickness measurements.[48]

Further, our result was in accordance with that of the study by Kheshie et al.,[22] who compared the effect of HILT and low level laser therapy (LLLT), in addition to exercise in both groups, and found significantly better results of reduced pain and WOMAC scores in the HILT and exercise group over the LLLT and exercise group.[22] Moreover, another study conducted on 53 male KOA patients confirmed that patients treated with HILT showed better results than with conventional physical therapy and exercise therapy regarding tested dependent variables (VAS, active knee flexion, timed up and go test, DW6m, and WOMAC scores) after 12 weeks.[25] In addition, Kim et al.[29] explored the impact of HILT on pain and function in 20 patients with KOA. Subjects were randomly allocated to an HILT group (who received 12 HILT and CPT sessions) and a control group (who received CPT). HILT showed significantly lower values than the control group in VAS and WOMAC scores.[27]

In addition, HILT has powerful, excellent, and immediate analgesic efficacy in KOA patients.[26] HILT significantly decreased pain levels, measured by VAS and dolorimetry, after seven sessions of HILT in comparison with sham laser treatment.[23] In partial agreement with our results, the effectiveness of HILT in combination with glucosamine and chondroitin sulfate (GCS) in KOA was investigated by Alayat et al. on 67 subjects. The level of pain, knee function improvements, synovial thickness (ST), and femoral cartilage (FCT) thickness were evaluated. The authors did not identify major variations in VAS or WOMAC scores between the third and sixth months of treatment. A substantial drop in ST was observed in the HILT group after 6 weeks of therapy, with significant decreases in the comparison groups, GCS or exercises with placebo HILT groups, and no significant variations in medial and lateral FCT across all groups.[24]

These results can be clarified by the laser's effect on tissues as the Nd:YAG pulsed laser can rapidly produce photochemical and photothermal effects, with a wavelength of 1.064 nm and peaks of up to 8.000 W, pulsed emissions, and frequent peaks with brief periods, and pause intervals, to reduce thermal accumulation in the tissue.[49] These characteristics contribute to a greater radiation spread in tissues with low histological risk, which results in the likelihood of deep tissues and structures being treated. By adjusting the pulse strength and frequency, the photothermal effect can also be regulated for patient protection and comfort.[50] HILT has been shown to alleviate inflammatory and pain symptoms. Underlying reasons for analgesic and anti-inflammatory actions of laser therapy remain unclear. The performance of HILT is assumed to be a consequence of the unique high peak capability (up to 3 kW) of the laser pulse with a relatively low frequency and pulse duration. This high peak power supplies a significant amount of energy and eliminates thermal accumulation phenomena for a short period. HILT can therefore produce deep tissue photothermal and photochemical effects. These effects can enhance the development of collagen in the tissue and enhance blood flow, cell metabolism, and vascular permeability, thereby lowering pain and fixing damaged cartilage tissues.[51,52]

Limitations and recommendations

As a result, this study has some limitations. Since no control groups were used in this study, placebo effects have not been tested. The underlying mechanism of ESWT has not been well defined to date. According to our clinical experience, the indications are mainly based on literature. No objective measurements were used to assess the knee's functional progress, but it was comparable with previous research on this issue. Since no placebo control groups were used in this analysis, no placebo effects were measured.

Further, the follow-up time was limited and the study did not show whether the gains in each category are for the long term. As a randomized control trial (RCT), the results of our study were encouraging, and we recommend comparisons with other common physical therapy modalities used in the treatment of KOA, such as low-frequency magnetic therapy. In addition, we recommend a more extended follow-up period after 3 and 6 months to clarify the extended effects of the study interventions.

Conclusions

For short-term effects on patients with KOA, HILT was shown to have a superior impact, with reduced pain and improved physical function and impairment, compared with ESWT.

Authors' Contributions

There are five authors who contributed to this work and they did all that was required to accomplish this work. There are no other researchers who participated in this work.

Author Disclosure Statement

The authors did not receive any financial support from any institution or company; it is their project and they insured all expenses. No competing interests exist.

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