

Effect of High Power Laser Therapy on Patients with Chronic Discogenic Sciatica: A Randomized Clinical Trial.

Abstract

Back ground: Sciatica is a frequent clinical illness that may be intensely painful, disabling, and life-altering.

Objectives: The goal of this research was to see how high-power laser therapy affects the intensity of pain, angle of straight leg raise, six-minute walk test and electrophysiological studies in patients with chronic discogenic sciatica.

Methods: A lumbar disc herniation at L5-S1 caused chronic unilateral sciatica in thirty-six male patients were included in this study. The patients have been divided into 2 identical groups [the control group (G1) and the study group (G2)] randomly. Participants in the control group (G1) got a designed physiotherapy program that included ultrasound, stretching exercise, back muscles strengthening exercise and sciatic nerve flossing technique. While patients in the study group (G2) got the same designed physiotherapy program as G1 plus high power laser therapy (HPLT). The outcome measures were latency and amplitude of Hoffmann reflex (H-reflex) for evaluating S1 nerve root function, visual analog scale (VAS) for evaluating pain level, angle of straight leg raise (SLR) and six-minute walk test (6MWT) for assessing functional impairment. Both groups were assessed before and after 4 weeks of therapy.

Results: The findings demonstrated that both groups showed a significant reduction in pain level and latency of H-reflex following therapy. The angle of SLR, 6-minute walking distance (6MWD), and the amplitude of the H-reflex all improved significantly in both groups. After therapy, the study group's VAS and H reflex latency were significantly decreased than the control group's ($p < 0.01$). In addition, the study group's 6MWD, angle of SLR, and H reflex amplitudes were significantly increased than the control group's ($p < 0.01$) following therapy.

Conclusion: High power laser therapy (HPLT) is a successful treatment for patients suffering from chronic discogenic sciatica.

Key words: Discogenic sciatica; Lumbar disc herniation; High power laser therapy; Hoffmann reflex; Visual analogue scale; Straight leg raise and six-minute walk test; 6-minute walking distance.

Introduction

Sciatica is a radicular leg pain that is localized to the dermatome of a pathologically affected nerve root. Discogenic sciatica is caused by lumbar disc herniation (LDH), which can lead to neurological dysfunctions like leg paresthesia, disability, leg pain, and low back pain ^{1,2}. In different regions, the predicted incidence of sciatica varies from 1.2 to 43% ¹. Discogenic

sciatica, which represents approximately 90% of sciatica cases, is the main source of illness; furthermore, it has a substantial economic effect owing to lost work and expensive healthcare expenditures^{3,4}.

During human movements, nerves are subjected to a variety of mechanical stresses. When the nerve is compressed, tense, or sheared beyond its capacity, the circulation and axoplasmic flow within the nerve are impeded, resulting in ischemia and lowered function^{5, 6}. Compressive stress is caused by disc herniations, which obstruct blood supply to the nerve root⁷. Motor and sensory dysfunction is caused by nerve root compressions^{8, 9}. Nerve root compression also causes alterations in the nerve's microvascular circulation as well as the release of inflammatory mediators, resulting in pain¹⁰. Furthermore, nerve root compression is linked to neural conduction block and intraneural edema^{11,12}.

The electrical equivalent of the monosynaptic stretch reflex can be measured as the Hoffmann reflex. The H-reflex is a valid indicator of spinal level motor neuron pool activity and a nerve root activity assessment^{13, 14}. The S1 nerve root compression is assessed using the H-reflex^{15, 16, 17}. The amplitude of the H-reflex decline on the entrapped side, prolonged latency, side-to-side latency variations, and lack of the H-reflex on the entrapped side are all considered diagnostic criteria for the H-reflex¹⁸. In individuals with radiculopathy, H-reflex latency prolongation or side-to-side variations may indicate neural demyelination caused by injury to large-diameter nerve axons. In the lack of extensive demyelination, however, reduced or absent amplitude of the H-reflex on the entrapped side may indicate nerve conduction block¹⁹.

The term LASER stands for Light Amplification by Stimulated Emission of Radiation. It's a device that uses stimulated emissions of electromagnetic radiation to generate coherent, collimated, and monochromatic light via an optical amplification process. Laser treatment employs light from the electromagnetic spectrum's red and infrared parts. Low power laser therapy (LPLT) is the usage of therapeutic lasers with a power of no more than 500mW (class 3B lasers), while high power laser therapy (HPLT) is the usage of therapy lasers having significantly more power (class 4 lasers)²⁰.

High power laser therapy (HPLT) is a new, painless, and powerful modality that has a substantial impact on pain reduction. The HPLT has photomechanical, photothermal, and photochemical capabilities, as well as a variety of therapeutic benefits such as analgesic, anti-edema, and biological stimulation²¹⁻²⁵. A further advantage of HPLT, particularly the neodymium-doped yttrium aluminum garnet laser, is its increased power and deep tissue penetration depth²⁶. HPLT clearly decreased levels of pain in acute and chronic disorders like carpal tunnel syndrome, chronic osteoarthritis, injuries to the knee, rheumatoid arthritis, shoulder pain, fibromyalgia, as well as pain after operations^{22, 27-30}.

There is no agreement in the literature regarding the frequency, pulse power, time of application, or energy dose of laser therapy in patients. There is a small amount of research now being conducted on the effectiveness of HPLT treatment on cervical radiculopathy, lateral

epicondylitis, knee arthritis, frozen shoulder, and post-mastectomy complications. The literature on HPLT therapy for chronic lumbar disc herniation is limited. As a result, we carried out this research to assess the efficacy and safety of HPLT in the therapy of chronic discogenic sciatica patients.

Materials and methods

Design:

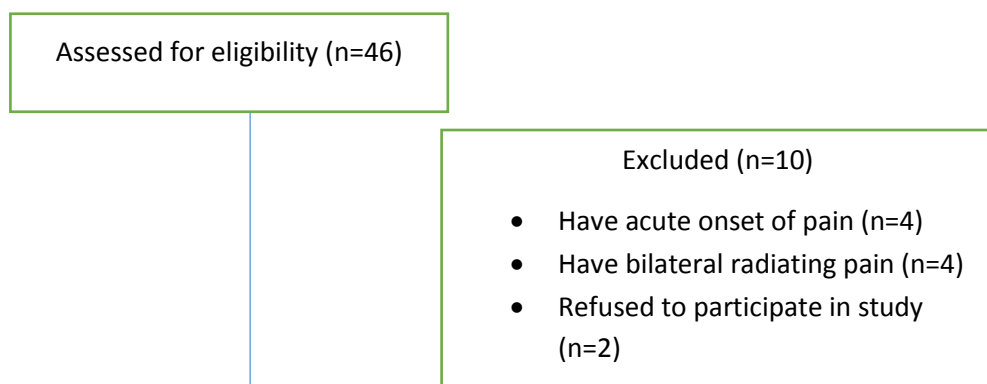
Single blinded randomized controlled clinical trial. The research took place at Faculty of Physical Therapy's Out-Patient Clinic at Cairo University and Faculty of Physical Therapy's Out-Patient Clinic at Badr University. This study was conducted at the period from March 2021 to June 2021.

Randomization:

Informed consent was signed by all participants in the study. Patients were randomly assigned into two groups using random generator (www.randomization.com). The randomized list was done by a research assistant not involved in the study, and the allocation to one of the two groups was revealed to the patients at the time of confirmation of enrolment. The participants have been divided into 2 equal groups at random: the control group (G1) and the study group (G2). The control group (G1) received treatment from a specially designed treatment program that included electrotherapy (ultrasound) and therapeutic exercises (stretching, strengthening exercises and sciatic nerve flossing technique). The study group (G2) received (HPLT) and the identical physical treatment program as group1. Three sessions per week for one month.

Patients

Thirty-six male patients had chronic unilateral sciatica findings from lumbar (L5-S1) disc herniation with pain for more than three months. The age of patients ranged from 22 to 44 years. Each patient was subjected to physical, neurological examination (motor assessment, sensory assessment) and electrophysiological assessment (H-reflex). The level of lesion was detected by magnetic resonance imaging (MRI). Patients having significant osteoporosis or lumbar injections in the previous four weeks, as well as those with acute trauma, inflammatory pain, lumbar instability, lumbar surgeries, and neurological problems, patients with serious illnesses, and patients having serious or uncontrolled cardiovascular, Other cases of sciatica as ligamentum flavum hyperatrophly, osteophyte formation or stenosis, as well as the patients with acute onset of pain (pain less than three months) and Patients with bilateral radiating pain were excluded^{24,31}.



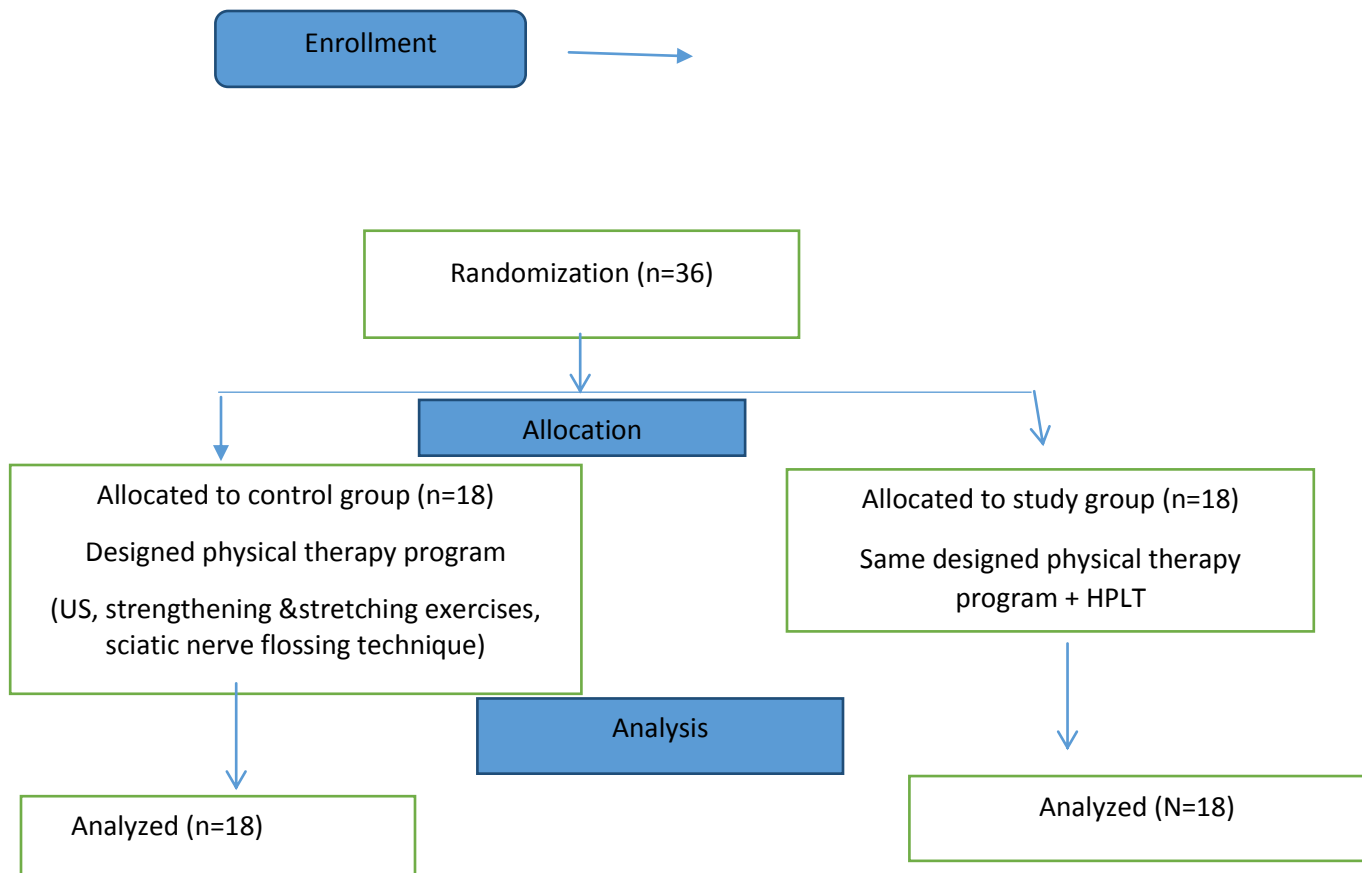


Figure 1 : Flow chart of study participant

Outcome measures and assessment procedures

A **visual analogue scale (VAS)** has been employed for measuring pain levels before and after treatment. Patients have been asked to rate their radicular pain on VAS. Patients select the level of their pain via putting a sign on a line (10cm), with 0 (no agony) and 10 (worst pain possible) indicating the endpoints of the VAS line. VAS is a valid and accurate measure for assessing chronic pain (interclass correlation coefficient (ICC) = 0.87)³².

Range of motion assessment of a straight leg raise (SLR) using a uni-level inclinometer (ISOMED). From a supine laying position on a flat plinth, in a neutral neck position, facing the side of the examiner. The examiner places one hand beneath the Achilles tendon while holding the inclinometer with the other. Throughout the SLR test, the examiner's hand must hold the inclinometer vertically between the index and middle fingers, with the center of the inclinometer positioned at the lower third of the tibia. The therapist prevented any knee flexion by lifting the leg perpendicular to the point where the patient reported pain.

Performance and Scoring of the 6-minute walk test (6MWT): The smartphone app-based self-measurement of the 6MWT is a convenient, reliable, and valid way to determine functional impairment in patients with lumbar radiculopathy³³. Participants were shown how to download and install the free 6MWT application, which utilizes standardized information sheets written in plain language and supplemented with figures and illustrations. In accordance with previous studies, those sheets also included directions on the ideal testing setting, which included a suitably long, straight, and reasonably flat path free of high-rises (or other things obstructing the GPS signal) and without obstructions (like red traffic signals). If any questions arise, a person and phone number have been provided to assist with the resolution. The 6MWT app determines the maximum walking distance in 6 minutes [6-minute walking distance (6MWD)], as the main outcome, with excellent accuracy.

Hoffmann reflex (H-reflex): Computerized Electromyography system (TOENNES Neuro Screen plus 1.70C) was used to electrically stimulate and record the soleus H-reflex. H-reflex has been measured in the soleus muscle by stimulating the tibial nerve with a one-millisecond pulse at 0.2pps of H-max. The peak-to-peak amplitude of the highest recorded H-reflex and the latencies of four spaced traces for both lower extremities have been averaged for each participant. The soleus H-reflex is evoked by tibial nerve stimulation in the popliteal fossa. The participants have been told to keep their legs and arms in the same position as much as possible during the test in order to get reliable H-reflex measurements. To prevent any intervention with the collected data, the knee joint was positioned in 20° flexion via placing a pillow below it. This caused the gastrocnemius muscle to relax. The skin over the calf area and the popliteal fossa behind the knee was cleaned by alcohol. In the midline, two centimeters distal to the gastrocnemius bifurcation and in line with the Achilles tendon, an active (black) recording electrode was placed. Three cm apart from the active electrode, a reference (red) recording electrode was placed. A ground electrode has been placed on the gastrocnemius between the recording and stimulating electrodes. The preamplifier and differential amplifier units of the electromyography (EMG) unit have been linked to the recording and ground electrodes. The stimulation electrode has been positioned longitudinally in the middle of the popliteal fossa, with the active electrode (cathode) positioned proximally and the anode positioned distally. The lower amplitude of electrical stimulation has been used to begin the strength of the stimulation, which was subsequently increased until plantar flexion of the foot appeared in response to electrical stimulation. Increase the stimulus intensity till you attain the maximal amplitude of the H-reflex (H maximum). In the lower extremity, four repeated H-maximums have been recorded (affected). It was decided to determine the average. The technique has been repeated for the other lower limb (sound) to contrast amplitudes and latencies as well as to record the difference in H-reflex latencies from side to side. The following were the electrical stimulating parameters: The stimulation duration is 0.5-1 ms, the stimulation rate is 1 pulse per 5 seconds (0.2 pps), and the stimulation intensity: subthreshold to action potential.

Treatment procedures

High power laser therapy

A Zimmer Opton pro, integrated High-power class IV laser device (serial N: 15200013306 & REF: 4682, made in Germany, manufactured by Zimmer MedizinSysteme), Zimmer Opton Pro emits energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature. The simultaneous application of laser light of two wavelengths (810 and 980nm) opens up a wide range of therapy options for the user. It was used in the present study. The device produces a maximum of 7 W power.

A single laser probe was utilized to provide laser radiation at dual wave lengths of 810 nm and 980 nm simultaneously, and a power density of 1 W/cm² duty cycle 1:1 to the. The apparatus was set manually to pulsed mode 40 J/cm² energy at the most painful points for 81 sec for each point. The laser was used in such cases with a constant movement. The overall energy applied to patients during a session was 400 J. Laser irradiation points: Five points on each side of the lower back was irradiated. The laser irradiation points were 2 cm laterally from spinous process at L1, L2, L3, L4 and L5 (right side), L1, L2, L3, L4 and L5 (left side). 3 sessions every other day per week for 4 weeks (12 sessions).

The subject was positioned in prone, exposing the treatment area and pillows kept under the head and legs for the relaxation; the lumbar area was scrubbed with an alcohol soaked gauze pad. During the therapy session, both the therapist and the patient wear safety goggles.

Designed physical therapy treatment:

Both groups of patients got a physical therapy program designed to treat LBP with S1 radiculopathy. It included therapeutic ultrasound as well as an exercise program that involved stretching exercises, strengthening exercises for back muscles and Sciatic nerve flossing technique. Ultrasound (Gymna Uniphy N.V) has been administered to the patient's lower back for 5 minutes at a frequency of 1 MHz in continuous mode at 0.5 W/Cm². Stretching exercises based on **Khalil et al**³⁴, back muscle strengthening exercises based on **Weinhardt and Heller**³⁵. The stretching exercises have been performed five times, each for 30 seconds, and the strengthening exercises have been performed five times in three sets, with 1 to 2 min of rest in between. The repetition of each exercise varied according to the physical ability of each patient. Sciatic nerve flossing technique was performed actively by the patients sitting on a chair or plinth. The patients were instructed to bend knee backwards under the plinth and simultaneously move the head backwards. Then the patients were instructed to straighten out the leg on the affected side and simultaneously move the head backward as if looking at the ceiling. The patients were instructed to lift the leg out and up in front until they experience pain and should not push beyond that point. As the nerve became less sensitive, the stretching effect was increased by instructing the patients to bring foot and toes in upward direction. Sciatic nerve flossing technique were given 5 sets of 15 repetitions with 1-minute rest in between sets³⁶.

Sample size calculation

The G*POWER statistical software (version 3.1.9.2; Franz Faul, Universitat Kiel, Germany) was used to calculate sample size based on H reflex amplitude data from a pilot study with 5 subjects in each group. For this study, 18 participants per group have been required. The following values have been used in the calculations: $\alpha=0.05$, $\beta=0.2$ effect size = 0.98 and ratio of allocation N2/N1 =1.

Statistical analysis

An unpaired t-test has been performed to compare participant characteristics across groups. The Shapiro-Wilk test has been utilized to ensure that the data has a normal distribution. To check that the groups were homogeneous, Levene's test for homogeneity of variances has been applied. VAS, 6MWD, SLR, and H reflex impacts have been compared within and across groups using a mixed design MANOVA. For the following multiple comparisons, post-hoc testing employing the Bonferroni correction has been performed. All statistical tests had a significance level of < 0.05 . The statistical package for social studies (SPSS) version 25 for Windows has been utilized to conduct all statistical analysis (IBM SPSS, Chicago, IL, USA).

- Results

- *Subject characteristics:*

The study and control groups' subject characteristics were shown in Table 1. Age, weight, height, and BMI did not differ significantly between groups ($p > 0.05$).

Table1. Comparison of study and control group subject characteristics:

	Mean \pm SD		MD	t- value	p-value
	Study group	Control group			
Age (years)	33.88 \pm 7.23	35.27 \pm 6.72	-1.39	-0.59	0.55
Weight (kg)	82.77 \pm 6.03	83.27 \pm 5.34	-0.5	-0.26	0.79
Height (cm)	177.11 \pm 3.69	176.5 \pm 3.79	0.61	0.49	0.62
BMI (kg/m²)	26.31 \pm 0.92	26.74 \pm 1.82	-0.43	-0.88	0.38

SD, Standard deviation; MD, Mean difference; p-value, level of significance

Treatment effects on VAS, 6MWD, SLR and H reflex:

Treatment and time interacted significantly ($F_{(5,30)} = 26.08$, $p = 0.001$, $\eta^2 = 0.81$). The main influence of time was significant ($F_{(5,30)} = 834.76$, $p = 0.001$, $\eta^2 = 0.99$). The major impact of treatment was not significant ($F_{(5,30)} = 1.64$, $p = 0.17$, $\eta^2 = 0.21$).

- Within group comparison

The study and control groups had a significant decrease in VAS and a significant increase in 6MWD and SLR following treatment compared to before treatment ($p > 0.001$). The percentage change of VAS, 6MWD, and SLR of the study group was 57.38, 80.85, and 48.1% respectively, and that of the control group was 47.05, 53.93, and 32.34% respectively (table 2).

The study and control groups had a significant increase in H reflex amplitude and a significant reduction in H reflex latency following treatment compared to before treatment ($p > 0.001$). The percentage change of H reflex amplitude and latency of study group was 190.4 and 13.39% respectively and that of control group was 97.26 and 9.44% respectively (table 3).

- Between groups comparison:

Before therapy, there were no significant differences across groups ($p > 0.05$). After therapy, the study group's VAS and H reflex latency were significantly decreased than the control group's ($p < 0.01$). In addition, after therapy, the study group's 6MWD, SLR, and H reflex amplitudes were significantly increased than the control group's ($p < 0.01$) (table 2,3).

Table2. Study and control groups' mean VAS, 6MWD, and SLR before and after therapy:

	Study group	Control group		
	Mean ±SD	Mean ±SD	MD (95% CI)	P-value
VAS				
Pre treatment	6.5 ± 0.85	6.61 ± 0.91	-0.11 (-0.71: 0.49)	0.71
Post treatment	2.77 ± 0.64	3.5 ± 0.85	-0.73 (-1.23: -0.21)	0.007
MD (95% CI)	3.73 (3.47: 3.97)	3.11 (2.85: 3.36)		

% of change	57.38	47.05			
	<i>p = 0.001</i>	<i>p = 0.001</i>			
6MWD (meters)					
Pre treatment	239.05 ± 30.72	247.61 ± 39.62	-8.56 15.46)	(-32.57:	0.47
Post treatment	432.33 ± 54.02	381.16 ± 46.93	51.17 85.44)	(16.88:	0.005
MD (95% CI)	-193.28 (-215.32: -171.23)	-133.55 (-155.59: -111.51)			
% of change	80.85	53.93			
	<i>p = 0.001</i>	<i>p = 0.001</i>			
SLR					
Pre treatment	45.61 ± 7.78	45.67 ± 9.06	-0.06 (-5.77: 5.66)		0.98
Post treatment	67.55 ± 7.02	60.44 ± 8.11	7.11 (1.96: 12.25)		0.008
MD (95% CI)	-21.94 (-23.65: -20.23)	-14.77 (-16.49: -13.07)			
% of change	48.1	32.34			
	<i>p = 0.001</i>	<i>p = 0.001</i>			

SD, Standard deviation; MD, Mean difference; CI, Confidence interval; p-value, Level of significance

Table 3. The study and control groups' mean H reflex amplitude and latency before and after therapy:

	Study group	Control group	MD (95% CI)	P-value
	Mean ±SD	Mean ±SD		
H reflex amplitude (mV)				
Pre treatment	1.98 ± 0.79	2.19 ± 1.18	-0.21 (-0.89: 0.47)	0.53
Post treatment	5.75 ± 0.85	4.32 ± 1.45	1.43 (0.62: 2.24)	0.001
MD (95% CI)	-3.77 (-4.05: -3.48)	-2.13 (-2.41: -1.84)		

% of change	190.4	97.26		
	<i>p = 0.001</i>	<i>p = 0.001</i>		
H reflex latency (ms)				
Pre treatment	33.67 ± 1.44	34.1 ± 1.69	-0.43 (-1.49: 0.63)	0.42
Post treatment	29.16 ± 1.82	30.88 ± 1.41	-1.72 (-2.82: -0.61)	0.003
MD (95% CI)	4.51 (4: 5.01)	3.22 (2.71: 3.72)		
% of change	13.39	9.44		
	<i>p = 0.001</i>	<i>p = 0.001</i>		

SD, Standard deviation; MD, Mean difference; CI, Confidence interval; p-value, Level of significance

Discussion

The results showed that pain level and latency of h-reflex were significant decreased while angle of SLR, 6MWD and amplitude of h-reflex complex were significant increased in patients suffering from chronic discogenic sciatica because of lumbosacral disc herniation when adding HPLT to a designed physical therapy program. HPLT has a more beneficial effect on improving patients' clinical and electrophysiological findings. To the author's knowledge, there have been no studies that show the HPLT's efficacy in the literature in patients with chronic discogenic sciatica on clinical and electrophysiological findings.

The improvement in the laser group is in agreement with the results of **Monici et al.**³⁷, who concluded that greater intensity laser therapy was utilized for a broad range of painful disorders, that the efficiency of laser therapy was shown in the therapy of several musculoskeletal conditions, and that laser is thought to have anti-edema, anti-inflammatory, analgesic, as well as reparative impacts.

The laser group's improvements might be related to HPLT's analgesic impact, which is dependent on various mechanisms of action, such as its capacity to reduce the transmission of pain stimuli and boost the body's production of morphine-mimetic compounds³⁸. Furthermore, it could have a direct impact on neuronal structures, potentially speeding up recovery from conduction block or inhibiting A δ - and C-fiber transmission³⁹. It also improves the flow of blood, vascular permeability, as well as cellular metabolism⁴⁰. The HPLT pain control is because of several mechanisms, such as the discharge of endogenous opioids, for example, the β endorphins in the CNS are expanded by HPLT treatment and these could diminish the pain sensations centrally, while substance P, which sensitizes pain transmitting neurons in the

peripheral nervous system, resulting in hyperalgesia, laser treatment reduces substance P discharge through the peripheral receptors^{41,42}.

The high power laser is a non-painful, non-invasive treatment method. It can stimulate regions that are hard to access using a low-power laser, like huge and/or deep joints²⁰. Patients have reported great pain reduction as a result of using the high-power laser^{43,44}.

Our results showed improvement in both groups, this is in line with **Alayat et al.**⁴⁵ who demonstrated that exercise treatment can clinically reduce pain, raise ROM, and enhance function. Emphasizing the significance of an active exercise program in rehabilitation focused on functional recovery is proven to be cost-effective, practicable, and safe. High intensity laser therapy (HILT) paired with exercise is more efficient and has a longer impact than sham laser with exercise or laser alone in improving lumbar ROM, reducing pain and functional impairment, with benefits lasting up to three months.

A study by **Kolu et al.**²⁴ revealed that using HILT in chronic lumbar radiculopathy patients, was effective treatment method as it decreased the VAS and Oswestry Disability Index scores four weeks after the treatment sessions, likewise, the findings of **Song et al.**⁴² indicated that HILT therapy for back and neck pain diminished pain and disability ratings significantly.

Fiore et al.²² established the short-term effects of high-intensity laser on lumbar pain in a trial of 30 patients, 15 of whom got US treatment and 15 of whom got laser treatment, which agreed with the findings of this study. The HILT group had significantly less pain and recovered disability following 3 weeks of therapy than the US group.

The findings of this research correspond with those of **Boyras et al.**²¹, who reported that HILT, ultrasound, and exercise have all been effective treatments for lumbar discopathy, but that HILT and ultrasound had a prolonged impact on some variables. For patients with lumbar disc herniation, HILT treatment may be a good alternate physiotherapy agent.

These results are supported by the study of **Gocevskaja et al.**⁴⁶, who conducted a study comparing the impact of two physical methods, high-intensity laser therapy and ultrasound treatment, in the therapy of patients having chronic low back pain. Patients experiencing chronic low back pain who were managed with a high-intensity laser had significantly decreased low back pain and disability as well as increased ROM, according to this study. Its beneficial effects continued for 3 months. Treatment of patients having chronic low back pain, HILT seems to be a successful, safe, and beneficial physical technique.

Conclusion: The study showed that both groups (control and study) had a significant reduction in pain level and latency of H-reflex following therapy. The angle of SLR, 6MWD, and the amplitude of the H-reflex all significantly improved in both groups. In the study group, VAS and H reflex latency were significantly lower than the control group. In addition, the study group's 6MWD, angle of SLR, and H reflex amplitudes were significantly higher than the control group's

following therapy. So this research's findings reveal that high-power laser treatment is beneficial in reduction of pain, functional impairment and increasing the physiological function of the nerve root and degree of straight leg raise.

Limitations: All of the participants were men. As a result, additional research involving both women and men is advised. There was no follow-up, and the findings were merely in the short-term. Another drawback is the absence of a placebo group.

Competing interests disclaimer: Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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