

Effect of Class IV Laser on Pain and Lumbar Canal Diameter Among Patients with Lumbar Disc Herniation: A Placebo Controlled Trial

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Abstract

Background: Lumbar disc herniation (LDH) is a common condition affecting working-age individuals, presenting with back pain. Class IV therapeutic laser therapy may help reduce inflammation, promote intervertebral disc healing and may increase the anterior-posterior (AP) diameter of the lumbar canal, providing pain relief.

Purpose: This study aimed to evaluate the effect of Class IV therapeutic laser in pain and lumbar canal diameter among patients with LDH.

Participants: 66 participants (59 males and 7 females) aged 30 to 60 years, all experiencing low back pain associated with LDH were included in the study.

Methods: This double-blinded, sham-controlled trial randomly assigned 66 participants into two groups (33 each). The experimental group received Class IV therapeutic laser (9W, 3780J), while the control group received a sham treatment. Both groups followed a regimen of hot pack, exercises, and lumbar corset. Pain with numerical pain rating scale (NPRS) and AP diameter of the lumbar canal with magnetic resonance imaging (MRI) were assessed at baseline and 10 weeks.

Results: Wilcoxon signed – rank test and Mann-Whitney U test were used for analysis. There was a significant decrease in NPRS score ($p=0.0001$) (mean 2.97 ± 1.36), and increase in lumbar canal AP diameter (mean 12.93 ± 3) in experimental group as compared to control group (mean 12.09 ± 1.63)

Conclusion: Class IV laser has been found effective in pain reduction and may improve canal diameter in LDH patients.

Implications: This study may aid in developing a treatment protocol for clinicians managing low back pain in LDH.

Keywords: Class IV Laser, Lumbar canal diameter, Lumbar disc herniation, Pain

INTRODUCTION

Among musculoskeletal issues, the lumbar region is particularly vulnerable, making low back pain (LBP) the second most widespread cause of discomfort, following headaches. Research suggests that nearly 80% of individuals in industrialized nations will experience LBP at some point in their lives, with around 10% developing chronic LBP. This condition typically begins in early life and reaches its peak prevalence in middle age [1, 2]. In most cases, LBP is associated with intervertebral disc disorders. Managing disc herniation effectively involves patient education, lumbar support, and physical therapy methods including electrotherapy and exercises. These approaches are essential for relieving pain, minimizing the risk of recurrence and chronic disability, and promoting a quicker return to daily activities. Recently, increased attention has been given to exercises and education on lumbar protection [2, 3].

Class IV high-intensity laser therapy (HILT) is a modern, non-invasive, and effective treatment modality known for its significant pain-relieving properties. Utilizing HIL radiation, Class IV HILT integrates photothermal, and photochemical effects, providing various therapeutic benefits such as anti-oedema, analgesic, and biological stimulation [3-6]. A notable advantage of Class IV HILT is its superior power and deep tissue penetration [7]. This therapy has been demonstrated to effectively reduce pain associated with both acute and chronic musculoskeletal conditions and post-surgical pain [8, 9].

Additionally, laser therapy is believed to enhance haematopoiesis in the bone marrow [8]. Unlike other treatment methods, lasers do not significantly alter tissue temperature, indicating that their physiological effects are not heat-dependent. Recent studies have emphasized the role of laser therapy in enhancing tissue regeneration, stimulating bone formation, supporting cartilage synthesis, and promoting extracellular matrix production [10, 11]. Research also suggests that laser supports tendon and ligament healing while preventing fibrosis formation [3, 12].

Though researches are available on effect of Class IV laser on Lumbar disc herniation (LDH) patients, however there is a paucity of studies that shows its effect on size of disc bulge by improving lumbar canal. The objective of this study is to investigate the impact of Class IV HILT on pain relief and the increase in lumbar canal anteroposterior (AP) diameter.

METHODS

This double-blind, randomized, placebo-controlled trial was conducted at Jindal Physiocare, New Delhi, in collaboration with Amity University, Noida, and involved a total of 66 participants, comprising 59 males and 7 females, aged between 30-60 years. All participants had been diagnosed with LDH and were experiencing L5-S1 radiating pain. The study was meticulously designed to adhere to rigorous ethical standards, including obtaining ethical approval from Amity University's Institutional Ethics Committee (IEC number: AUUP/IEC/2021-JAN/13) and registering with the Clinical Trials Registry of India (CTRI/2021/12/038661). Furthermore, the study was carried out in accordance with biomedical research ethics, the 2013 amended "Declaration of Helsinki", and "The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)" criteria. Following a comprehensive verbal explanation and in accordance with the Ethics Committee's guidelines, written consent was acquired from each participant to guarantee participant safety and informed consent.

We used G*Power, a statistical software program made for power analysis, version 3.1.9.7, to calculate the necessary sample size for our investigation. We calculated that in order to find a statistically significant effect, at least 40 participants would be required. This estimate was derived from an effect size (d) of 0.95, which represents a large effect, as well as an α error probability of 0.05, which is a conventional threshold for statistical significance. Furthermore, we aimed to achieve a power ($1-\beta$) of 0.90, indicating that we wanted to be 90% confident in detecting a statistically significant effect if it existed.

However, to account for potential participant dropouts during the study, we increased the sample size by 20% to ensure adequate statistical power. As a result, the final sample size was set at 66 participants, providing a buffer against potential attrition and ensuring the reliability of our findings. Eligibility was reconfirmed by magnetic resonance imaging (MRI) evidence of herniated lumbar discs and any associated neurological symptoms, such as hypoesthesia or paresthesia. Exclusion criteria were comprehensive, disqualifying individuals with a history of spinal surgery (including discectomy), spondylolisthesis, primary lumbar canal stenosis, spinal fractures, spinal tumors or malignancies, current pregnancy, any implants in the lumbar region, or tattoos over the area designated for treatment.

Following eligibility confirmation, participants were randomly assigned to the experimental or placebo group via an onsite computer-generated randomization method. Demographic variables, including BMI, age, weight, and height, were documented for each participant.

Participants in the experimental group received Class IV HILT via the LiteCure LCT-1000 system, a solid-state laser operating at 980/810 nm with a peak power of 10 W. The treatment involved delivering 3780 J over 7 minutes, applied to the affected lumbar spinal segment. The placebo group received laser for same time but intensity was turned off.

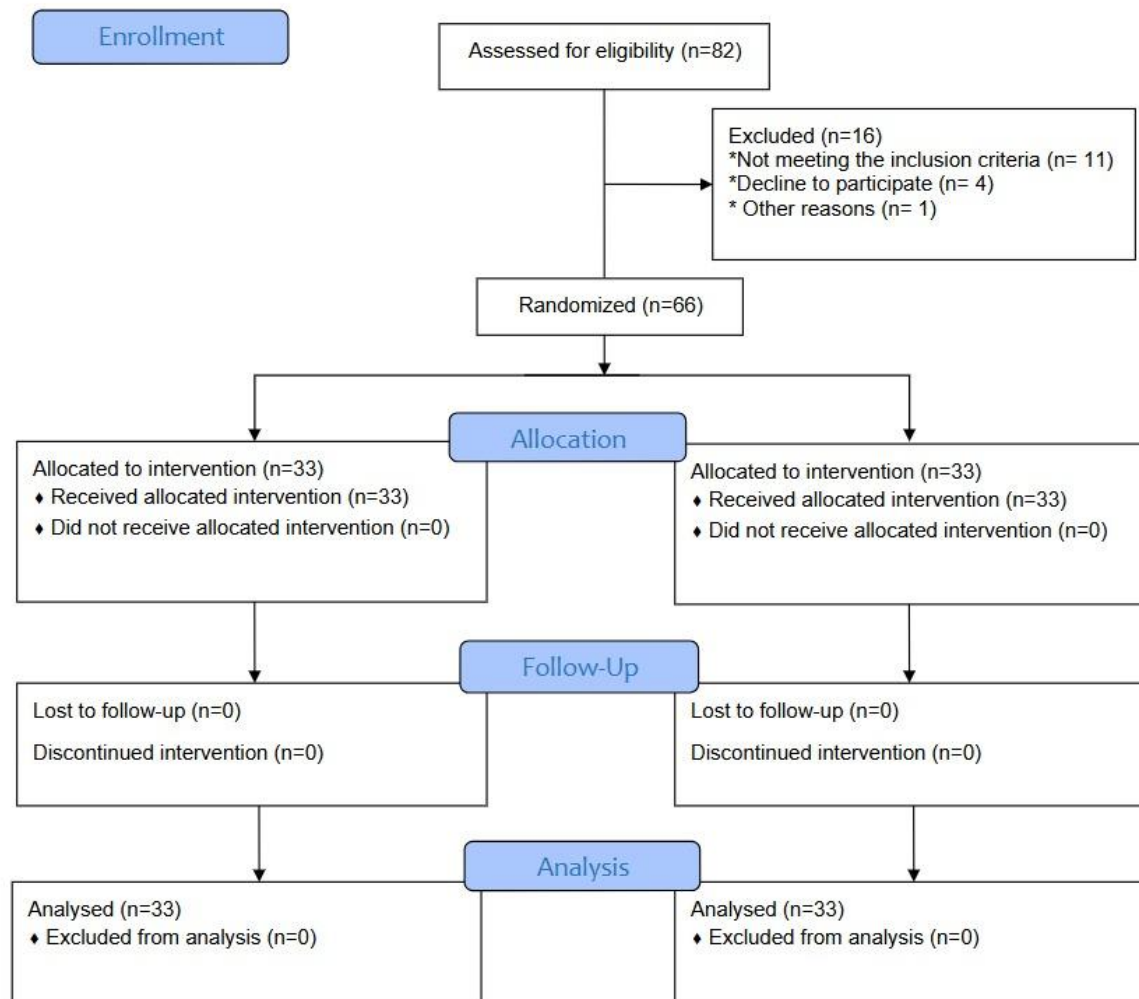
Both groups underwent standard physical treatment, which involved applying a hot pack to the lumbar area for ten minutes at 40°C. This was followed by a planned exercise regimen. Prone laying, prone on elbows, prone press-ups, prone arm raises, standing extensions, cat-camel stretches, bridging, wall squats, supine twists, and back isometrics were among the activities. Ten repetitions of each exercise were done, followed by ten seconds of rest and hold. Three times a week for ten weeks, the entire therapy session lasted forty-five minutes.

The Numeric Pain Rating Scale (NPRS), a well-established and reliable tool for assessing pain perception, was utilized to measure pain intensity. The scale ranges from 0 (no pain) to 10 (worst possible pain) [16]. Furthermore, to assess treatment outcomes, the AP diameter of the lumbar canal was evaluated using lumbosacral magnetic resonance imaging (MRI), providing an objective measure of structural changes in the affected spinal region.

Data analysis

IBM SPSS Statistics Version 23 was utilized for data analysis in this study. Descriptive statistics were applied to summarize the data, presenting results in tabular form as the mean ($\bar{X}$) and standard deviation (SD). The Shapiro-Wilk test was conducted to assess the normality of data distribution. For statistical comparisons, the Mann-Whitney U test was used to analyze differences between groups, while the Wilcoxon signed-rank test was employed for within-group comparisons. A significance level of $p < 0.05$ was considered statistically significant.

CONSORT FLOW CHART



RESULTS

This trial encompassed 66 participants, including 59 males and 7 females, as detailed in consort flow chart. These individuals fell within an age bracket of 30-60 years, and the average age was represented as 39.77 ± 7.23 years. The participants' mean weight, height, and body mass index were recorded as 75.16 ± 11.52 kg, 169.67 ± 5.31 cm, and 26.08 ± 3.49 kg/m², respectively.

Both groups exhibited a statistically significant reduction in NPRS scores following treatment ($p = 0.0001$). However, the Class IV HILT group demonstrated a more substantial decrease in pain intensity, as reflected by a greater reduction in VAS scores compared to the control group. Additionally, a statistically significant difference was observed between the two groups, with the Class IV HILT group achieving superior outcomes (mean 2.97 ± 1.36), as detailed in Tables 1 and 2 and illustrated in Graph 1.

Regarding the secondary outcome, the AP diameter of the lumbar canal showed improvement in the experimental group, with a mean value of 12.93 ± 3 . However, between-group comparisons did not reveal

a statistically significant difference in AP diameter improvement ($p > 0.05$), as presented in Tables 3 and 4 and depicted in Graph 2.

Table 1: Shows the within-group analysis of pain before and after the study duration

Pain (NPRS score)	Group									
	Control (N=33)					Experiment (N=33)				
	Mean	SD	Median	WSR (z)	p-value	Mean	SD	Median	WSR (z)	p-value
Pre-treatment	6.36	1.62	6.00	5.179	0.0001	6.03	1.10	6.00	4.846	0.0001
Post treatment	4.94	1.62	5.00			2.97	1.36	3.00		
N= number of participants, WSR= wilcoxon signed rank, SD=standard deviation, and NPRS= numeric pain rating scale										

Table 2: Shows between group analysis of pain before and after the study duration

Pain (NPRS score)	Group							
	Control (N=33)			Experiment (N=33)				
	Mean	SD	Median	Mean	SD	Median	Mann-Whitney U (z)	p-value
Pre-treatment	6.36	1.62	6.00	6.03	1.10	6.00	0.889	0.374
Post treatment	4.94	1.62	5.00	2.97	1.36	3.00	4.592	0.0001
N= number of participants, SD=standard deviation, and NPRS= numeric pain rating scale								

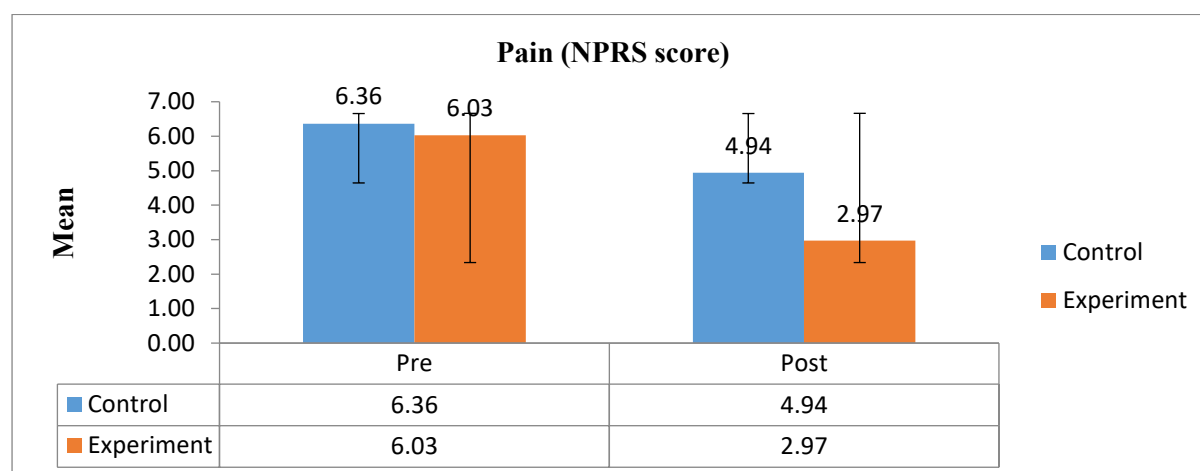
Table 3: Shows the within-group analysis of AP lumbar canal diameter before and after the study duration

Lumbar canal diameter L5-S1(mm)	Group									
	Control					Experiment				
	Mean	SD	Median	WSR (z)	p-value	Mean	SD	Median	WSR (z)	p-value
Pre-treatment	12.10	1.64	12.00	0.16	0.873	12.77	2.99	12.00	4.154	0.000
Post treatment	12.09	1.63	12.10			12.93	3.00	12.10		
AP= antero-posterior, N= number of participants, WSR= wilcoxon signed rank, SD=standard deviation, and NPRS= numeric pain rating scale										

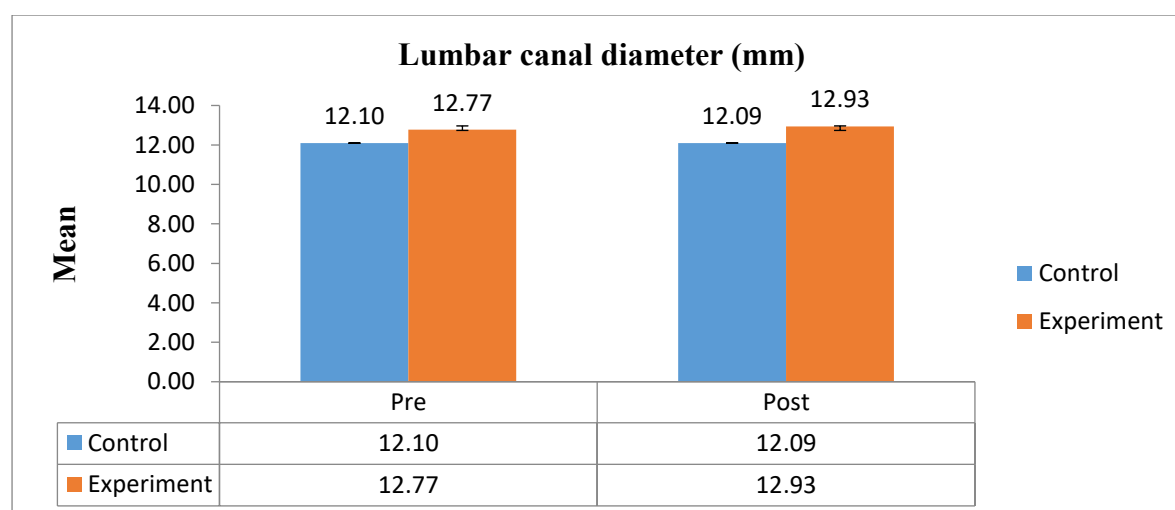
Table 4: Shows the between group analysis of AP lumbar canal diameter before and after the study duration

Lumbar canal diameter L5-S1(mm)	Group							
	Control			Experiment				
	Mean	SD	Median	Mean	SD	Median	Mann-Whitney U (z)	p-value
Pre Treatment	12.10	1.64	12.00	12.77	2.99	12.00	0.591	0.555
Post Treatment	12.09	1.63	12.10	12.93	3.00	12.10		

AP= antero-posterior, N= number of participants, SD=standard deviation, and NPRS= numeric pain rating scale



Graph 1: Baseline and after intervention scores of Pain using NPRS score of both the groups



Graph 2: Baseline and after intervention Lumbar canal AP diameter of both the groups

DISCUSSION

Our findings further strengthen the existing evidence base for the use of Class IV HILT in pain reduction. This study aligns with previous research demonstrating the potential of laser therapy to enhance functional outcomes in individuals with musculoskeletal conditions [13, 14]. The mechanism of action of Class IV HILT involves deep tissue penetration, facilitating photo biomodulation, which helps reduce inflammation, relieve pain, and accelerate tissue repair [15]. Additionally, laser therapy enhances tissue repair by increasing vascularization, stimulating fibroblasts, promoting collagen production, and improving circulation—all essential for connective and neural tissue healing [14].

The findings of this study are further supported by Alayat & Atya (2014), who demonstrated that Class IV HILT effectively reduced pain in patients with LBP, mainly due to its anti-inflammatory properties [16]. However, in contrast to present study, Gur A et al. (2003) found no significant of low-level laser therapy along with stabilization exercises on low back pain [17]. This highlights the importance of power output and wavelength while choosing modality.

This study has demonstrated a marginal improvement in the lumbar canal AP diameter in patients diagnosed with LDH. Recent research has increasingly implicated laser therapy in various regenerative processes, including the repair and formation of tissues, and the synthesis of new cartilage tissue along with its matrix. Additionally, laser therapy has been shown to promote the healing of tendons and ligaments while playing a crucial role in preventing the formation of fibrosis. Given these biological effects, it is plausible that laser therapy may contribute to structural improvements in the lumbar spine, including the enhancement of the AP canal diameter, which could have potential implications for alleviating symptoms associated with LDH. [3, 16]

The findings of this study are further corroborated by Chen et al. (2018), who demonstrated that Class IV HILT enhances lumbar segment function, improves the angle of straight leg raising, and provides long-lasting therapeutic benefits with practical clinical applications. [18].

The lack of robust evidence regarding diagnostic procedures and treatment interventions for a condition as prevalent as degenerative lumbar radiculopathy is concerning. Published trials often suffer from imprecise patient selection, with lumbar radiculopathy not being confirmed through MRI [19].

While the findings of this study are promising, several limitations must be considered, we can explore its effectiveness on other lumbar disc level as well as for cervical spine. Long term follow up with MRI to observe the effect may also be observed. These factors underscore the necessity for further research involving larger patient cohorts and long-term treatment protocols to comprehensively evaluate the durability and clinical applicability of Class IV HILT in management of LDH [20].

The inclusion of a placebo group is essential for distinguishing the specific effects of Class IV HILT on LDH. Without this control, it becomes challenging to ascertain whether the observed improvements result directly from the laser treatment or are influenced by other factors, such as the natural progression of the condition. The potential impact of the placebo effect on subjective symptom relief must also be considered when interpreting results. Furthermore, emerging evidence suggests that HILT may provide greater therapeutic benefits compared to low-level laser treatment, highlighting the need for further research to optimize treatment parameters [21].

However, further large-scale studies with prolonged treatment durations are essential to solidify its role as a reliable non-invasive treatment to confirm these findings and optimize patient care.

CONCLUSION

In conclusion, this study highlights the potential of Class IV HILT as an effective non-invasive treatment for LDH, demonstrating significant pain reduction and possible improvements in the lumbar spinal canal diameter. The analgesic effects, driven by photo biomodulation, inflammation reduction, and tissue repair by improving vascularization support its role as a valuable adjunct to conventional treatments.

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REFERENCES

1. Manchikanti L. Epidemiology of low back pain. *Pain Physician*. 2000 Apr; 3(2):167-92. PMID: 16906196.
2. Katz JN. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. *J Bone Joint Surg Am*. 2006 Apr; 88 Suppl 2:21-4. doi: 10.2106/JBJS.E.01273. PMID: 16595438.
3. Boyraz I, Yildiz A, Koc B, Sarman H. Comparison of high-intensity laser therapy and ultrasound treatment in the patients with lumbar discopathy. *Biomed Res Int*. 2015; 2015:304328. doi: 10.1155/2015/304328. Epub 2015 Mar 25. PMID: 25883952; PMCID: PMC4390181.
4. Fiore P, Panza F, Cassatella G, Russo A, Frisardi V, Solfrizzi V, Ranieri M, Di Teo L, Santamato A. Short-term effects of high-intensity laser therapy versus ultrasound therapy in the treatment of low back pain: a randomized controlled trial. *Eur J Phys Rehabil Med*. 2011 Sep; 47(3):367-73. Epub 2011 Jun 8. PMID: 21654616.
5. Venosa M, Romanini E, Padua R, Cerciello S. Comparison of high-intensity laser therapy and combination of ultrasound treatment and transcutaneous nerve stimulation in patients with cervical spondylosis: a randomized controlled trial. *Lasers Med Sci*. 2019 Jul; 34(5):947-953. doi: 10.1007/s10103-018-2682-7. Epub 2018 Nov 15. PMID: 30443883.
6. Kolu E, Buyukavci R, Akturk S, Eren F, Ersoy Y. Comparison of high-intensity laser therapy and combination of transcutaneous nerve stimulation and ultrasound treatment in patients with chronic lumbar radiculopathy: A randomized single-blind study. *Pak J Med Sci*. 2018 May-Jun; 34(3):530-534. doi: 10.12669/pjms.343.14345. PMID: 30034410; PMCID: PMC6041553.
7. Pagé MG, Katz J, Stinson J, Isaac L, Martin-Pichora AL, Campbell F. Validation of the numerical rating scale for pain intensity and unpleasantness in pediatric acute postoperative pain: sensitivity to change over time. *J Pain*. 2012 Apr; 13(4):359-69. doi: 10.1016/j.jpain.2011.12.010. Epub 2012 Mar 15. PMID: 22424915.
8. Özdemir F, Birtane M, Kokino S. The clinical efficacy of low-power laser therapy on pain and function in cervical osteoarthritis. *Clin Rheumatol*. 2001; 20(3):181-4.
9. Brouwer PA, Peul WC, Brand R, Arts MP, Koes BW, van den Berg AA, van Buchem MA. Effectiveness of percutaneous laser disc decompression versus conventional open discectomy in the treatment of lumbar disc herniation; design of a prospective randomized controlled trial. *BMC Musculoskelet Disord*. 2009 May 13; 10:49. doi: 10.1186/1471-2474-10-49. PMID: 19439098; PMCID: PMC2697136.
10. Arisu, H.D., Türköz, E. & Bala, O. Effects of Nd:Yag laser irradiation on osteoblast cell cultures. *Lasers Med Sci* 21, 175–180 (2006). <https://doi.org/10.1007/s10103-006-0398-6>
11. Spivak JM, Grande DA, Ben-Yishay A, Menche DS, Pitman MI. The effect of low-level Nd:YAG laser energy on adult articular cartilage in vitro. *Arthroscopy*. 1992; 8(1):36-43. doi: 10.1016/0749-8063(92)90133-v. PMID: 1550649.

12. Fortuna D., Rossi G., Paolini C., Magi A., Losani F., Fallaci S., et al. (2002). The Nd:YAG pulsed wave laser as support therapy in the treatment of teno- desmopathies of athlete horses: a clinical and an experimental trial. *PROGRESS IN BIOMEDICAL OPTICS AND IMAGING*, 4903, 105-118 [10.1117/12.486622].
13. Ahmad MA, Moganan M, A Hamid MS, Sulaiman N, Moorthy U, Hasnan N, Yusof A. Comparison between Low-Level and High-Intensity Laser Therapy as an Adjunctive Treatment for Knee Osteoarthritis: A Randomized, Double-Blind Clinical Trial. *Life (Basel)*. 2023 Jul 6; 13(7):1519. doi: 10.3390/life13071519. PMID: 37511894; PMCID: PMC10381799.
14. Maeda T. Morphological demonstration of low reactive laser therapeutic pain attenuation effect of the gallium aluminium arsenide diode laser. *Laser Ther*. 1989; 1(1):23-6.
15. Gocevska M, Nikolikj-Dimitrova E, Gjerakaroska-Savevska C. Effects of High - Intensity Laser in Treatment of Patients with Chronic Low Back Pain. *Open Access Maced J Med Sci*. 2019 Mar 25; 7(6):949-954. doi: 10.3889/oamjms.2019.117. PMID: 30976338; PMCID: PMC6454183.
16. Alayat MSM, Aly THA, Elsayed AEM, Fadil ASM. Efficacy of pulsed Nd:YAG laser in the treatment of patients with knee osteoarthritis: a randomized controlled trial. *Lasers Med Sci*. 2017 Apr; 32(3):503-511. doi: 10.1007/s10103-017-2141-x. Epub 2017 Jan 11. Erratum in: *Lasers Med Sci*. 2020 Oct; 35(8):1875. doi: 10.1007/s10103-020-03088-x. PMID: 28078503.
17. Gur A, Karakoc M, Cevik R, Nas K, Sarac AJ, Karakoc M. Efficacy of low power laser therapy and exercise on pain and functions in chronic low back pain. *Lasers Surg Med*. 2003; 32(3):233-8. doi: 10.1002/lsm.10134. PMID: 12605431.
18. Chen L, Liu D, Zou L, Huang J, Chen J, Zou Y, Lai J, Chen J, Li H, Liu G. Efficacy of high intensity laser therapy in treatment of patients with lumbar disc protrusion: A randomized controlled trial. *J Back Musculoskelet Rehabil*. 2018 Feb 6; 31(1):191-196. doi: 10.3233/BMR-170793. PMID: 28854500.
19. Hasvik E, Haugen AJ, Grøvre L. Symptom descriptors and patterns in lumbar radicular pain caused by disc herniation: a 1-year longitudinal cohort study. *BMJ Open*. 2022 Dec 22; 12(12):e065500. doi: 10.1136/bmjopen-2022-065500. PMID: 36549718; PMCID: PMC9772640.
20. Choi HW, Lee J, Lee S, Choi J, Lee K, Kim BK, Kim GJ. Effects of high intensity laser therapy on pain and function of patients with chronic back pain. *J Phys Ther Sci*. 2017 Jun; 29(6):1079-1081. doi: 10.1589/jpts.29.1079. Epub 2017 Jun 7. PMID: 28626329; PMCID: PMC5468204.
21. Ahmad MA, Moganan M, A Hamid MS, Sulaiman N, Moorthy U, Hasnan N, Yusof A. Comparison between Low-Level and High-Intensity Laser Therapy as an Adjunctive Treatment for Knee Osteoarthritis: A Randomized, Double-Blind Clinical Trial. *Life (Basel)*. 2023 Jul 6; 13(7):1519. doi: 10.3390/life13071519. PMID: 37511894; PMCID: PMC10381799.