

Efficacy of Low-level Laser Therapy on Motor Recovery and Functional Independence among Individuals with Incomplete Spinal Cord Injury: A Randomised Controlled Trial

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ABSTRACT

Introduction: Incomplete Spinal Cord Injury (ISCI) results in permanent neurological deficits, leading to challenges in self-care, respiration, sphincter management, motor function and overall functional ability. Despite advancements in the treatment of spinal cord injuries, many individuals still experience motor deficits and struggle with functional independence, significantly lowering their quality of life and limiting their capacity for independent living. Low-Level Laser Therapy (LLLT) has been shown to be effective in neuroprotection, including cell regeneration, Schwann cell activation, cell growth, reduction of spasticity and improvement of various functions. However, its effectiveness in enhancing these functional domains in individuals with incomplete spinal cord injuries remains underexplored.

Aim: To assess the effectiveness of LLLT on motor recovery and functional independence among individuals with ISCI.

Materials and Methods: This randomised controlled trial was conducted at the Indian Spinal Injury Centre in Vasant Kunj under Amity University Noida from January 2023 to November 2024. A total of 104 participants who had suffered ISCI between six months to one year prior to enrollment and were classified as grade C or D were recruited. The experimental group received

LLLT, while the control group received placebo LLLT on nine points around the fractured vertebrae. Both groups underwent conventional therapy. Evaluations were performed at baseline and after four weeks of intervention using amplitude-based surface Electromyography (EMG) on the lower extremities to assess motor recovery and the Spinal Cord Independence Measure (SCIM) to evaluate improvements in self-care, respiratory function, sphincter management and mobility. The normality of the data was checked using the Kolmogorov-Smirnov test. Paired t-tests and Independent t-tests were conducted within and between the groups, respectively, using a p-value of ≤ 0.05 .

Results: Both groups showed improvement; however, the experimental group demonstrated better improvement in EMG scores in the majority of the muscles of the lower extremity compared to the control group, suggesting a positive impact on motor recovery. SCIM scores indicated significant improvement within the groups, but non significant differences were found between the groups regarding self-care, respiratory function, sphincter management and mobility.

Conclusion: The study indicated that LLLT had a positive effect on motor recovery and functional independence. These findings may serve as an effective measure for both clinicians and the patient community.

Keywords: Disability evaluation, Spinal cord injuries, Surface electromyography

INTRODUCTION

The ISCI results in a partial loss of motor and sensory function due to spinal cord damage. Individuals with ISCI often experience a range of functional impairments, particularly in self-care, respiration, sphincter management and mobility, which significantly impact their quality of life and independence [1]. Rehabilitation for these individuals typically involves various interventions aimed at improving functional independence. EMG has emerged as a promising intervention, offering diagnostic insights and therapeutic benefits, such as biofeedback and muscle re-education. EMG holds the potential to restore voluntary muscle control, alleviate spasticity and improve outcomes related to mobility and sphincter function [2]. The Spinal Cord Injury Independence Measure (SCIM-III) is a validated tool for assessing functional abilities in individuals with spinal cord injuries, particularly in domains such as self-care, respiration, sphincter management and mobility [3].

However, the efficacy of LLLT using sEMG and SCIM-III in improving these domains, especially for ISCI remains insufficiently studied. Despite its promise, there is a dearth of research examining the combined impact of SCIM and EMG, particularly for ISCI.

There are two reasons why LLLT has not become widely accepted, despite its application in treating a wide range of ailments. First, it is still considered an experimental method because the underlying biochemical mechanisms remain unclear. Second, each therapy requires adjusting a number of parameters, such as the administered wavelength fluence, pulse shape and timing of the applied light. The viability of the treatment may be diminished, or poor outcomes may result from incorrect parameter settings. Incorrect light sources and measurements are to blame for many of the negative effects associated with LLLT. Additionally, LLLT exhibits a biphasic dose response, meaning that lower light dosages often work better than higher ones.

This study aimed to provide a greater understanding of how LLLT should be applied to a spinal cord injury area and its effectiveness. The current protocol was designed to test the efficacy of LLLT in conjunction with conventional therapy to improve motor impairment and functional independence.

LLLT has shown significant results in enhancing physical performance in individuals with central nervous system disorders, resulting in improved sensorimotor recovery and quality of life. However, there

is a limited number of studies and clinical trials, with some yielding encouraging results. To date, no randomised controlled trials have been conducted to identify the most effective LLLT protocol for the ISCI population. Despite this, there is currently no established standard treatment to evaluate the impact of LLLT at an 810 nm wavelength on functional independence and motor recovery.

This two-armed randomised controlled trial aimed to evaluate the effectiveness of LLLT, using EMG and SCIM-III, in improving motor recovery, self-care, respiratory function, sphincter management and mobility in individuals with ISCI.

To our knowledge, little is known about how long the effects of LLLT last, which is crucial for determining how frequently LLLT would need to be administered to slow or prevent the progression of impairments caused by SCI. Moreover, it is unclear what the ideal site for non invasive irradiation is, given the pattern of neurodegeneration in incomplete SCI. The photochemical effects of LLLT, which is believed to be an immersive technology, have not yet been optimised for the appropriate dosage for SCI patients. In studies on LLLT [4-7], the sites most frequently targeted were over the transverse processes and spinous processes of the vertebrae, the same stimulation sites used for the treatment of myelomeningocele [8].

Present study hypothesised that LLLT would improve motor impairment and functional independence in patients with incomplete SCI. This study aims to provide a greater understanding of how LLLT should be administered to a spinal cord injury area. Thus, the present study aims to assess the effectiveness of LLLT on motor recovery and functional independence among individuals with incomplete SCI. The objectives were to investigate the effect of LLLT on lower extremity motor recovery and functional independence in individuals with incomplete SCI.

MATERIALS AND METHODS

This randomised controlled trial was conducted at the Indian Spinal Injury Centre in New Delhi, India with ethical approval from Amity University, Noida, from January 4, 2023, to November 30, 2024. The study protocol adheres to the principles outlined in the Standard Protocol Items Recommendation for Interventional Trials (SPIRIT). The Indian Spinal Injuries Centre (Ref: ISIC/RP/2023/024) and Amity University's institutional ethical committee (AUUP/IEC/JULY/2022) have approved the study protocol, which has also been registered with the Clinical Trials Registry-India (CTRI/2023/04/052093). This study followed the 2017 National Code of Ethics for Biomedical Research Involving Human Participants and the 2013 revised Declaration of Helsinki.

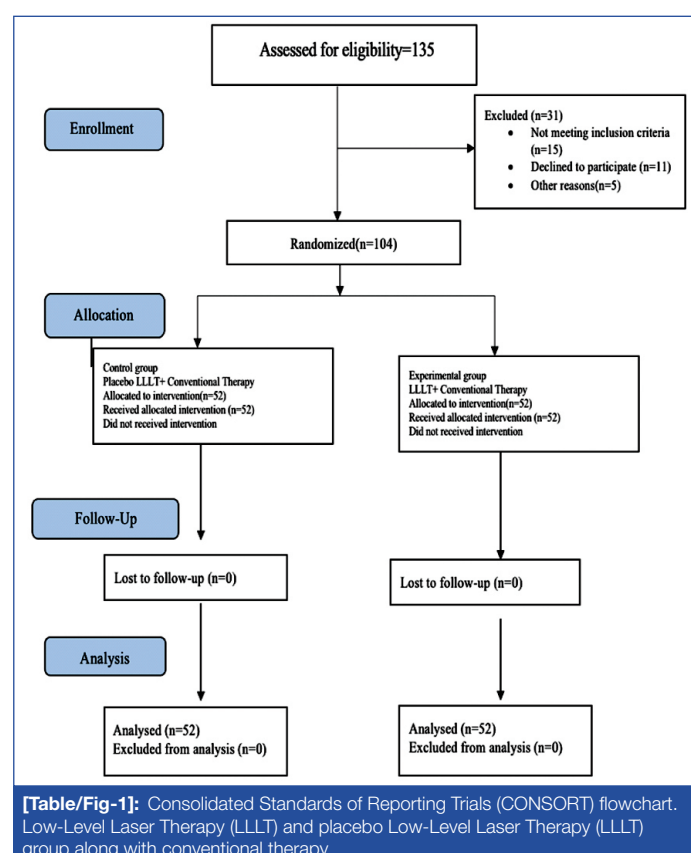
Before recruiting any participants, patient information sheets were provided to every subject and written informed consent was collected. Participants were recruited based on eligibility criteria and demographic data were collected.

Sample size calculation: To evaluate the improvements in the outcome measures in both groups, a sample size estimate was conducted. The sample size was calculated using G*power version 3.1.2 software. An effect size of $d=0.805$ [6], $\alpha=0.05$, and a power level of 0.95 were established. Additionally, it was determined that the final sample size would be $N=104$ after accounting for a 20% dropout rate. One hundred four adults aged 18-45 years with a diagnosis of ISCI (American Spinal Injury Association Impairment Scale (ASIA) grades C or D) [9] were recruited.

Inclusion criteria: Participants who have suffered from spinal cord injury 6 months to 1 year before enrollment [10]. To be eligible, participants must be classified as Grade C or D, and the level of injury should be between T2 and L5 according to the ASIA Impairment Scale. They should be aged between 18 and 45 years, regardless of gender, and diagnosed with ISCI [11]. A score of 5/5 for the upper extremity muscles on the physical assessment test through the ASIA scale indicates adequate motor function in the upper extremities.

Exclusion criteria: Patients will be excluded from the study if they had complete spinal cord injury, significant cognitive impairment, contraindications to LLLT, or a history of any underlying neurological or musculoskeletal condition that could complicate treatment. Subjects with any history of transient ischaemic attack, stroke, or other medical illnesses will also be excluded. Additionally, subjects with any skin problems, such as rashes or skin allergies [12], were excluded from the study.

Randomisation and intervention: A computer-based randomisation process, developed using random allocation software by an individual other than the investigator, will be used to conduct the randomisation for individuals who have already been enrolled [13]. The CONSORT flow chart provides information about the randomisation process. Participants will be randomly assigned to either the control group, which will receive placebo LLLT plus conventional therapy, or the experimental group, which will receive LLLT plus conventional therapy, using a computer-generated randomisation sequence. Both groups will receive laser therapy three times per week for four weeks [Table/Fig-1].



During a screening visit, various assessments will be conducted, including assessments using amplitude-based surface EMG [14] and SCIM, which consists of three domains: Domain 1 (Self-care) assesses the patient's independence with daily tasks, including eating, bathing, dressing and grooming. Domain 2 (Respiration and Sphincter Management) includes assistance with coughing, secretion clearance, positioning and sphincter management (including use of a toilet). Domain 3 assesses the patient's mobility both indoors and outdoors, with and without assistance [15]. A written and verbal explanation of the trial's objectives, potential risks, costs, benefits and the right to withdraw will be provided to all prospective trial participants before screening. Confidentiality will be upheld when collecting, managing and storing data. The complete trial dataset will be available to all authors. Participants will not be permitted to take part in any other rehabilitation or research procedures during the study that might affect its results.

Blinding: The allocation of groups was blinded to the assessor and only the principal investigator was aware of the group assignments.

The treatment group designation was not known to the researchers conducting the data analysis.

Conventional therapy: Physiotherapists, who were blinded to the outcomes of the assessments and the assignment of patients to the placebo and LLLT groups, carried out the same physiotherapy exercises each week, as detailed in [Table/Fig-2]. The exercises included chair-to-bench transfer training, sitting-to-standing training, stretching and strengthening exercises for all joints of the bilateral lower limbs, practice mat activities, cycling, standing in a parallel bar, practicing various daily activities, core strengthening, standing balance exercises, posture care, gym activities and fall prevention. Each conventional therapy session lasted 60 minutes and was conducted over four weeks [16-18].

Type of activity	Frequency	Intensity	Time duration (Minutes)
1. Warm-up phase 2. Seated marching 3. Shoulder shrugs 4. Side bends 5. Biceps curl 6. Neck rotations	4 weeks	10 reps/min/ exercise for 2 minutes each. 2 min rest period between the exercises	18 minutes
Rest for 3 minutes between the activity			
Lower extremity strength and Core strength training 1. Motorised cycling 2. Standing frame activities 3. Balance exercises in sitting and standing 4. Passive ROM for all joints for bilateral lower limb 5. Mat exercises for bed mobility	4 weeks	10 reps/min/ exercise for 2 minutes each. 2 min rest period between the exercises	18 minutes
Rest for 3 minutes between the activity			
Cool-down phase 1. Seated marching 2. Shoulder shrugs 3. Side bends 4. Biceps curl 5. Neck rotations	4 weeks	10 reps/min/ exercise for 2 minutes each. 2 min rest period between the exercises	18 minutes

[Table/Fig-2]: Conventional therapy.

Experimental protocol: In the experimental group, participants were assigned to receive LLLT (Digi-laser 203, HMS Medical Systems) in the lateral decubitus position. Nine locations around the area of vertebral damage were targeted, starting from the midpoint of the fractured vertebra (F) to the right facet of the fractured vertebra, then to the left facet of the fractured vertebra, followed by the first caudal vertebra in relation to the fractured vertebra, the left facet of the first caudal vertebra, the right facet of the first caudal vertebra, then to the second caudal vertebra in relation to the fractured vertebra, and finally to the right and left facets of the second caudal vertebra. Every 60 seconds over the course of nine minutes, the device emitted a sound to indicate the beginning and end of the radiation emission. All participants underwent 12 sessions over four weeks, during which they also performed conventional therapy exercises daily [Table/Fig-3]. The protocol was the same for both groups, but no irradiation was emitted in the control group [5,6,19].

Parameters	Infrared laser
Wavelength (nm)	810 nm
Operating mode	Continuous
Mean radiant energy (mW)	120
Polarisation	Random
Exposure time (s)	60 (per point), 540 (total)
Number of points irradiated	9
Application method	Contact
Number and frequency of treatment sessions	Times per week for 4 weeks (total 12 sessions)

[Table/Fig-3]: Low-Level Laser Therapy (LLLT) parameters.

Outcome measures: The primary outcome measure included Amplitude-based Surface EMG (SEMG) assessments of muscle activity in key areas (e.g., iliopsoas, quadriceps, tibialis anterior, extensor hallucis longus and gastrocnemius) to monitor improvements in muscle function [20,21]. The secondary outcome measure was the SCIM, which evaluates self-care, respiratory function, sphincter management and mobility. Clinical evaluations were conducted at baseline and after four weeks of intervention [3,15,22].

STATISTICAL ANALYSIS

The normality of the data was checked using the Kolmogorov-Smirnov test. Independent t-tests were conducted to examine mean differences between the experimental and control groups for SEMG and SCIM scores, while paired t-tests were used to evaluate within-group changes from baseline to post-intervention. A significance level of p-value <0.05 was considered statistically significant.

RESULTS

The mean age of participants was 34.24±5.61 years, with a distribution of 29.8% female and 70.2% male. There were no significant demographic differences between the experimental and control groups at baseline [Table/Fig-4].

Parameters		Control group	Experimental group	Total	p-value
Gender	Males	36 (69.2%)	37 (71.2%)	73 (70.2%)	0.830
	Females	16 (38.8)	15 (28.8%)	31 (29.8%)	
Age (years)		34.45±5.16	34.06±5.61	34.24±5.61	0.730
Time since injury (in months)		8.17±1.67	8.33±1.78	8.25±1.17	0.649
Height (cm)		166.73±5.25	166.48±6.97	166.61±6.14	0.837
Weight (kg)		69.60±8.68	73.10±9.98	71.35±9.47	0.059

[Table/Fig-4]: Demographic data in control and experimental group.

Change in EMG Scores between and Within Control and Experimental Group

Both the right and left iliopsoas muscles showed significantly higher baseline EMG scores in the experimental group compared to the control group. The p-values for these comparisons were 0.027 (right) and 0.006 (left), indicating a statistically significant difference, with the experimental group demonstrating greater muscle activity at baseline.

The experimental group also exhibited significantly higher EMG scores for both the right (p-value=0.001) and left quadriceps (p-value=0.004) when compared to the control group at baseline. This suggests that individuals in the experimental group had greater motor recovery activity in these muscles before the intervention.

The right tibialis anterior muscle showed no significant difference at baseline (p-value=0.084), while the left tibialis anterior muscle had a p-value of 0.393, indicating no significant differences between the groups in the pre-intervention phase for these muscles.

No significant differences were observed between the two groups in the pre-intervention phase for either the right (p-value=0.078) or left (p-value=0.273) extensor hallucis longus muscles.

For the gastrocnemius muscles, the experimental group showed a trend toward higher activity in the right (p-value=0.093) but no significant difference in the left (p-value=0.705) at baseline, suggesting no clear differences in these muscles before intervention.

Postintervention, the experimental group demonstrated significantly higher EMG scores for both the right (p-value=0.001) and left (p-value=0.001) iliopsoas muscles compared to the control group. This indicates that the experimental group led to greater muscle activation following the intervention.

Significant improvements were observed in the quadriceps muscles in the experimental group, with both the right (p-value=0.001) and left

(p-value=0.005) showing higher EMG activity compared to the placebo group. This suggests that experimental group therapy had a positive effect on the activation of the quadriceps muscles postintervention.

Both the right (p-value=0.002) and left (p-value=0.045) tibialis anterior muscles showed significant improvements in the experimental group compared to the control group, indicating that experimental group therapy had a favourable impact on the activation of these muscles following the intervention.

The experimental group also showed significantly higher EMG scores post-intervention for both the right (p-value=0.002) and left (p-value=0.009) extensor hallucis longus muscles. This indicates that experimental group therapy was more effective than control group therapy in enhancing the activation of these muscles.

For the gastrocnemius muscles, the right gastrocnemius showed a significant difference (p-value=0.038) with higher EMG activity in the experimental group. However, the left gastrocnemius did not show a significant difference (p-value=0.084), indicating a trend toward improvement in the experimental group but lacking statistical significance.

The experimental group exhibited significantly higher EMG activity compared to the control group in several key muscle groups, including the iliopsoas, quadriceps, tibialis anterior and extensor hallucis longus muscles, both at baseline and after the intervention. Postintervention, the experimental group demonstrated greater muscle activation in these muscles, particularly in the iliopsoas, quadriceps and tibialis anterior.

The gastrocnemius muscles showed a mixed response, with significant improvement on the right side but no significant difference on the left side. Overall, these findings suggest that the experimental group had a positive impact on muscle activation, which may contribute to improved mobility and functional independence in individuals with ISCI.

The statistically significant differences observed, particularly for the iliopsoas and quadriceps muscles, support the efficacy of the experimental treatment as a promising assessment tool. Further investigation into long-term outcomes and additional muscle groups could provide a more comprehensive understanding of its effects. Both treatments—LLLT and placebo LLLT—combined with conventional therapy led to statistically significant improvements in muscle measurements, suggesting that both interventions had positive effects [Table/Fig-5].

Muscles		N	Control group Mean±SD	Experimental group Mean±SD	Between group p-value
Iliopsoas-R	Pre	52	337.83±257.91	455.73±278.40	0.027
	Post	52	437.11±262.55	606.73±237.68	0.001
Within group	p-value	--	<0.001	<0.001	---
Iliopsoas-L	Pre	52	290.54±225.26	430.02±278.91	0.006
	Post	52	444.61±237.32	601.18±243.40	0.001
Within group	p-value	--	<0.001	<0.001	---
Quadriceps-R	Pre	52	338.56±274.98	543.60±341.89	0.001
	Post	52	492.72±291.38	686.88±282.38	0.001
Within group	p-value	--	<0.001	<0.001	---
Quadriceps- L	Pre	52	373.33±275.26	545.48±324.33	0.004
	Post	52	513.69±279.75	672.89±280.34	0.005
Within group	p-value	--	<0.001	<0.001	---
Tibialis anterior-R	Pre	52	232.46±241.14	332.10±334.34	0.084
	Post	52	422.35±270.20	601.52±294.30	0.002
Within group	p-value	--	<0.001	<0.001	---
Tibialis anterior-L	Pre	51	275.87±302.11	334.39±385.87	0.393
	Post	52	446.37±296.38	567.67±313.10	0.045
Within group	p-value	--	<0.001	<0.001	---

Extensor hallucis longus-R	Pre	52	254.58±289.48	368.65±360.26	0.078
	Post	52	434.96±291.82	623.50±320.11	0.002
Within group	p-value	--	<0.001	<0.001	---
Pre-extensor hallucis longus-L	Pre	52	279.79±287.48	352.59±380.16	0.273
	Post	52	420.31±271.78	575.61±320.01	0.009
Within group	p-value	--	<0.001	<0.001	---
Pre-gastrocnemius-R	Pre	52	306.69±299.16	412.78±338.23	0.093
	Post	52	461.35±286.23	591.52±342.16	0.038
Within group	P value	--	<0.001	<0.001	---
Pre-gastrocnemius-L	Pre	52	324.48±318.90	348.93±337.45	0.705
	Post	52	475.65±307.05	585.52±334.32	0.084
Within group	p-value	--	<0.001	<0.001	---

[Table/Fig-5]: EMG scores between and within control and experimental group. Paired t-test, level of significance p<0.05, R: Right, L: Left. (Even after distribution, the Result of Pre values and post values in iliopsoas-R and Quadriceps have shown differences. However, the effect size have shown the strength as small effect size in iliopsoas R pre value (Effect size: 0.214) post value (Effect size: 0.320), Quadriceps R pre value (Effect size: 0.313) post value (Effect size: 0.320), Quadriceps L pre value (Effect size: 0.275) post value (Effect size: 0.273))

Change in SCIM Scores between and Within Experimental and Control Group

Before the intervention, there were no significant differences in total SCIM scores between the experimental group and the control group. The mean total SCIM score in the experimental group was 59.33±17.35, while in the control group, it was 57.50±18.17 (p-value=0.601). However, after the 4-week intervention period, both groups demonstrated improvements in total SCIM scores, with the experimental group showing a greater mean increase. Although the postintervention improvement in both groups was not statistically significant (p-value=0.363), the experimental group did exhibit a larger mean increase.

The SCIM score increased in the experimental group from pre to postintervention (59.33±17.35 to 69.15±15.86). The p-value for the change in total SCIM scores is <0.001, which was highly statistically significant. This indicates a significant improvement in the functional abilities of the participants in the experimental group after the intervention. The experimental group demonstrated a mean increase of 9.82 points, with a statistically significant improvement (p-value <0.001).

Both treatment groups showed significant improvements in their total SCIM scores from pre- to postintervention (p-value <0.001 for both), suggesting that both experimental and control group therapies contributed positively to the participants' functional abilities. However, the experimental group exhibited a slightly larger increase in total SCIM scores, implying that the combination of LLLT with conventional therapy may be more effective in enhancing self-care, mobility and other functional abilities in individuals with ISCI [Table/Fig-6].

Outcome measures		N	Control Mean±SD	Experimental Mean±SD	Between group p-value
PRE-SCIM Total	Pre	52	57.50±18.17	59.33±17.35	0.601
	Post	52	66.15±17.56	69.15±15.86	0.363
Within group	p-value	---	<0.001	<0.001	---
PRE-SCIM Domain 1 (self-care)	Pre	52	13.27±4.63	13.69±4.43	0.635
	Post	52	15.12±3.87	15.44±3.79	0.665
Within group	p-value	---	<0.001	<0.001	---
PRE-SCIM domain 2 (Respiration and Sphincter Management)	Pre	52	30.75±8.50	31.56±8.42	0.628
	Post	52	33.65±7.6	33.73±6.94	0.957
Within group	p-value	---	<0.001	<0.003	---
PRE-SCIM Domain 3 (Mobility- Room and Toilet)	Pre	52	14.08±8.30	14.50±8.16	0.794
	Post	52	17.67±9.16	19.98±8.33	0.182
Within group	p-value	---	<0.001	<0.001	---

[Table/Fig-6]: SCIM scores between and within experimental and control group. Independent t-test, Level of significance p<0.05, SCIM: Spinal cord independence measures

DISCUSSION

In this randomised controlled trial, authors compared the effects of LLLT on motor recovery and functional abilities in individuals with ISCI. The results of this study demonstrate that LLLT leads to better improvements in motor recovery and functional outcomes compared to the placebo LLLT.

Improvements in Motor Recovery

The baseline EMG measurements showed significant differences between the experimental and control groups, with the experimental group exhibiting higher muscle activation in key muscle groups, including the iliopsoas, quadriceps, tibialis anterior and extensor hallucis longus muscles. This suggests that participants in the experimental group had greater neuromuscular function at baseline, which may have contributed to the larger improvements observed postintervention. These baseline differences could reflect variations in the severity of spinal cord injury or previous rehabilitation efforts and may need to be considered when interpreting the results.

The findings of the present study indicated a marked improvement in lower extremity motor scoring at postintervention, as evidenced by the results from using an independent t-test within the groups. After a 4-week LLLT intervention, participants in the experimental group experienced improvements in motor recovery in key muscles, such as the iliopsoas, quadriceps, tibialis anterior, extensor hallucis longus and gastrocnemius, compared to the control group.

Interestingly, postintervention, the experimental group demonstrated significantly higher EMG scores for several key muscle groups, particularly the left iliopsoas (p-value=0.001) and right iliopsoas (p-value=0.001), as well as for the left quadriceps (p-value=0.001) and right quadriceps (p-value=0.005). This indicates that LLLT had a substantial impact on enhancing muscle activation in muscles involved in mobility. The tibialis anterior and extensor hallucis longus muscles also showed significant improvements in muscle activation in the experimental group. However, the gastrocnemius muscles exhibited mixed results. While the right gastrocnemius showed significant improvement in muscle activation (p-value=0.038), the left gastrocnemius did not (p-value=0.084). This suggests that the effect of LLLT on some muscle groups may be more pronounced than on others, possibly due to differences in muscle function and the level of spinal injury.

The greater improvements in the Lower Extremity Motor Score (LEMS) in the experimental group can be attributed to the LLLT intervention, which has been documented in many studies to improve muscle strength not only in the ISCI population, but also in individuals with stroke, traumatic brain injury, degenerative brain disease, spinal cord injury and peripheral nerve regeneration (Hashmi JT et al., 2010; Silva T et al., 2021) [4,8]. The authors propose that low intensity, appropriate location and dosage may be the reasons for the enhancement in muscle strength observed after 12 sessions of LLLT.

A possible explanation for these improvements could be the repetitive irradiation applied to specific sites, which may have activated the spinal nerves that escaped damage (hibernating neurons) and reorganised the remaining neural circuits, thus improving the lower extremity muscle score. The mechanism behind the improvements in motor recovery could be attributed to the stimulatory effects of LLLT on tissues, which enhance mitochondrial functions through increased synthesis of ATP, reactive oxygen species and the activity of Cytochrome C-Oxidase (CCO). CCO is the main enzyme in the mitochondrial respiratory chain that converts oxygen into energy through mitochondrial oxidative phosphorylation. An increase in CCO activity results in improved oxygen uptake and energy metabolism [23].

This photon bioenergetic effect induces metabolic and haemodynamic changes that help neurons function better because oxygen metabolism is crucial for neurons. From the spinal cord's ventral horn, inferior

motor neurons innervate the muscles of the skeleton. The axons of these neurons form the ventral roots, which join with the dorsal roots (that transmit sensory information) to either form mixed spinal nerves or project through spaces between the vertebrae. The inferior motor neurons are classified as alpha and gamma neurons and are responsible for innervating muscle fibers and generating force in muscles. A motor unit is formed by the motor neuron and the extrafusal muscle fibers it innervates; the number of muscle fibers that comprise a motor unit varies depending on the muscle and its specialisation in performing specific movements [4].

Hashmi JT et al., conducted a review to examine the effects of LLLT on neurological conditions such as stroke, traumatic brain injury, degenerative brain disease, SCI, and peripheral nerve regeneration. Their study also reported that LLLT had no adverse effects [4]. Da Silva FC et al., conducted a randomised clinical trial involving 25 patients with ISCI to evaluate the effects of LLLT. The results demonstrated that LLLT stimulated the injured tissue, resulting in improved motor responses. EMG data showed differences compared to the preintervention evaluation, indicating higher mean frequency (MDF) values at rest and during isotonic contraction 30 days after the treatment ended [5].

Additionally, Da Silva FC et al., carried out another randomised sham-controlled clinical trial involving 30 participants with ISCI. This study showed improvements in sensitivity and motor skills using the ASIA Impairment Scale and Quality of Life (QoL) assessed using the WHOQOL-BREF questionnaire before and after LLLT treatment during 12 sessions, where irradiation was applied in contact with the skin over the spinous processes of the vertebrae at five points marked above the injury in lateral decubitus at a wavelength of 808 nm for 12 sessions over four weeks. Compared to the sham group, LLLT treatment improved motor skills and QoL in the active group, with results sustained at the one-month follow-up [6].

Mohammadzadeh E et al., conducted a quasi-experimental matched-pair design study to estimate the therapeutic effects of Photobiomodulation (PBM) on Bone Mineral Density (BMD) in patients with complete spinal cord injury (C.SCI) and osteoporosis (OP) using follow-up Dual-Energy X-Ray Absorptiometry (DEXA). The results showed significant improvements in BMD in the PBM group, both at proximal femur and mid-distal forearm locations compared to the control group [7].

Amplitude is related to the firing and synchronisation of motor units. An increase in amplitude can indicate either an improvement in the firing synchronisation of the motor units or an increased firing frequency of the motor units. Thus, LLLT may contribute to improvements in motor recruitment. The activity of a motor neuron is controlled by three pathways that modulate different aspects of its activity [24,25]. The first pathway involves ganglion cells of the dorsal root that relay information about the length of the muscle innervated by the alpha neuron. The second pathway is essential for initiating the control of voluntary movement and arises from motor neurons in the brainstem and motor cortex. The third pathway consists of interneurons in the spinal cord, which are responsible for spinal motor programs. It can be suggested that LLLT in this study promoted the firing of motor neurons through the early activation of the third pathway of inferior motor neurons, as demonstrated by the increase in the amplitude of the EMG signal. A review of the literature revealed no studies that employed amplitude analysis in patients with incomplete spinal cord injury [26,27].

This was the first randomised controlled trial in which the role of LLLT was evaluated in patients with ISCI. The results demonstrate that LLLT stimulated the injured tissue, leading to an improved motor response. These findings are consistent with previous research that has highlighted the beneficial effects of LLLT on muscle function and rehabilitation outcomes in individuals with SCI [28,29].

Improvements in Spinal Cord Independence Measures (SCIM-III)

After the 4-week intervention, the experimental group showed significant improvements in their total SCIM-III scores, demonstrating a larger mean increase of 9.82 points compared to the control group. While the postintervention improvement in both groups was not statistically significant (p -value=0.363), the results indicate that both therapies were effective in enhancing functional abilities as measured by the SCIM-III.

These results align with preclinical studies that have shown LLLT can foster neural regeneration, improve synaptic plasticity and promote axonal growth. LLLT exerts its effects at molecular, cellular and tissue levels [30]. The primary mechanism behind these effects is believed to involve the absorption of red and near-infrared (NIR) light by mitochondrial chromophores, particularly Cytochrome C Oxidase (CCO), which is part of the respiratory chain within the mitochondria. Additionally, photoacceptors in the cell plasma membrane may play a role. This absorption triggers a series of events within the mitochondria, leading to the bio-stimulation of various processes. Spectral data obtained for CCO in different oxidation states have been shown to match the activity spectra associated with biological responses to light [31,32].

It is hypothesised that light absorption may result in the photodissociation of inhibitory nitric oxide from CCO, thereby enhancing protein activity, electron transport, mitochondrial respiration and ATP production [33]. In turn, LLLT alters the cellular redox state, activating multiple intracellular signaling pathways and influencing transcription factors involved in cell proliferation, survival, tissue repair and regeneration. By providing a non invasive method to stimulate these biological processes at the cellular level, LLLT may address some of the limitations of conventional rehabilitation therapies, potentially leading to more significant functional recovery [33,34].

This aligns with previous studies that have indicated that LLLT can provide beneficial effects on functional recovery, possibly due to its ability to enhance tissue healing and reduce pain, thereby facilitating more effective rehabilitation [35-37].

The experimental group exhibited greater improvement, suggesting that LLLT may have an added benefit in enhancing self-care, mobility and functional independence. Despite the overall improvements in SCIM-III scores in the experimental group compared to the control group, there were no statistically significant differences in postintervention domain-wise scores (p -value=0.05 for all domains). However, both groups showed significant improvements within each domain (self-care, respiration and sphincter management and mobility) (p -value=0.001), which underscores the positive effects in improving motor recovery, self-care, respiration, sphincter management and mobility.

Nevertheless, neither group stood out in terms of demonstrating a significantly greater improvement within any specific domain. This may suggest that the sham LLLT also contributed effectively to the rehabilitation process, even though the experimental group showed a greater overall improvement.

To the best of our knowledge, this was one of the first randomised controlled trials to explore the effects of LLLT on improving muscle strength and functional independence in individuals with incomplete spinal cord injuries. It is also one of the very few studies to investigate the impact of LLLT combined with conventional therapy on lower extremity muscle scores and functional independence. LLLT is a low-cost, commercially available therapeutic intervention that provides irradiation stimulation in a safe environment and offers significant therapeutic value for many other neurological conditions. The results of this randomised controlled trial highlight that the combined effects of LLLT and conventional therapy can lead to

considerable improvements in muscle strength and functional independence.

By applying the findings of this study, physical therapists may achieve substantial improvements in the rehabilitation of motor recovery and functional independence in individuals with incomplete spinal cord injuries. Future studies should focus on determining the appropriate dosage and location of irradiation to help design better rehabilitation protocols. Additional studies could also include assessments of other muscle groups to understand the impact of LLLT on the overall motor recovery of participants. Future research should investigate the long-term effects of LLLT on functional and motor recovery to better understand the sustained benefits of this treatment approach.

Limitation(s)

Several limitations must be considered when interpreting the findings. Firstly, this study assessed only short-term outcomes. Secondly, the study focused on specific muscle groups involved in mobility; further research should expand the investigation to include additional muscles and functional measures. Understanding how LLLT affects different muscle groups could provide insight into its role in comprehensive rehabilitation programs for individuals with SCI.

CONCLUSION(S)

The results of this study indicate that both LLLT and sham LLLT led to significant improvements in functional abilities and motor recovery in individuals with ISCI. The experimental group, however, demonstrated greater improvements in muscle activation, particularly in the iliopsoas and quadriceps muscles. These findings support the potential of LLLT as an effective intervention for enhancing functional recovery and mobility in individuals with incomplete SCI, warranting further investigation into its long-term effects and broader applications.

Authors' contribution: JS: Conceptualisation; JS, CK: Methodology and Supervision; DR, JS: Writing.

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