



Low-level laser therapy versus trunk stabilization exercises on sternotomy healing after coronary artery bypass grafting: a randomized clinical trial

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Abstract

The aim of this study was to investigate the effects of low-level laser therapy (LLLT) versus trunk stabilization exercises on sternotomy healing following coronary artery bypass grafting (CABG) surgery. Forty-five male patients who had acute sternal instability post-CABG surgery in the age range of 45–65 years were divided randomly into three equal groups ($n = 15$). The laser group received LLLT, while the exercise group received trunk stabilization exercises. The control group only received a routine cardiac rehabilitation programme, which was also provided to both the laser and the exercise groups. All groups were offered 12 sessions over 4 weeks. Sternal separation, median sternotomy photographic analysis, pain and activities of daily living (ADL) performance were evaluated pre- and post-treatment. Statistical significance was set at $P < 0.05$. There was a significant decrease among the laser group in upper-sternal separation, while the exercise and control groups showed a non-significant decrease. In terms of mid-sternal separation, laser and exercise groups showed a significant decrease while the control group showed a non-significant decrease. In terms of lower-sternal separation, the exercise group showed a significant decrease, while the laser and control groups showed a non-significant decrease. Post-treatment between-groups analysis showed a significant difference only among the laser and control groups with regard to upper-sternal separation, while analysis of the laser, exercise and control groups in the case of upper-sternal separation and the between-groups comparison in terms of mid- and lower-sternal separation revealed no significant differences. LLLT and trunk stabilization exercises were found to be the most effective methods for sternotomy healing post-CABG surgery, with LLLT offering superior performance in the case of the upper sternum while trunk stabilization exercises were more effective for the lower sternum.

Keywords Coronary artery bypass grafting · Low-level laser therapy · Sternotomy healing · Trunk stabilization exercises

Introduction

CABG surgery has been a well-preferred operation for patients with ischaemic heart disease since the 1970s [1]. In

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general, cardiac surgery is performed using a sternotomy technique. This incision results in substantial trauma for the patient [2] as its results in easy and excellent exposure to the heart and major vessels [3, 4]. Most patients undergoing CABG surgery as a first procedure require median sternotomy, with a few patients undergoing heart transplantations [5]. Following median sternotomy, there are healing complications such as sternal instability, non-union and wound infections. These problems are rare in the range of 0.3% to 5%, but destructive [6]. It has been reported that sternal motion and instability usually occur within the first 2 weeks after cardiac surgery, before healing is clinically significant [7].

Slow or impaired sternal healing is one of the probable complications experienced after heart surgery. Poor healing lengthens the patient's hospital stay, increases the costs of healthcare and delays the patient's recovery and return to job or social activities. Slow healing of the sternum usually results

in severe problems in terms of deep sternal wound infection [8, 9] mainly in the lower third of the sternum [10]. Considering the underlying non-physiological movement of the sternal edges, it is critical to promote guidelines for rehabilitation programmes in order to reduce extreme motion of the sternal edges, thereby decreasing patient symptoms. This is necessary for patients whose sternum cannot be repaired surgically [11].

LLLT applies bio-stimulatory effects to discrete cell types, which include osteogenic cells and bone tissue [12, 13]. Other effects of LLLT include increased alkaline phosphatase (ALP) activity and enhanced osteocalcin gene expression [14]. In general, there are systemic side effects from injected chemicals and other medications in the medical field; but, with laser therapy, there are no undesired effects on the patient's health quality [15].

Trunk stabilization exercises train and activate the abdominal and anterior thoracic cage muscles to assist in stabilizing the bisected sternum, thereby, decreasing undue motion in both the sagittal and the transverse planes during trunk movement. Patients' complain of pain and discomfort associated with sternal instability following cardiac surgery may be managed by diminishing the degree of this undue motion between the edges of the divided sternum, in turn providing a conservative treatment for sternal instability [16].

Limited research has been conducted to evaluate the effects of therapeutic modalities and non-pharmacological treatment on sternotomy healing post-CABG surgery [16, 17]. To the best of our knowledge, this is the first study to have been conducted in order to compare LLLT and trunk stabilization exercises and investigate which approach may lead to better sternotomy healing, a decrease in sternotomy pain and enhanced quality of life, thus improving the overall functional capacity of these patients and decreasing their comorbidities after CABG surgery.

Patients and methods

All of the patients signed a written declaration of informed consent relating to participation and the publication of results. The protocol for this study was approved by the local research ethics committee (NO: P.T. REC/012/001483) and registered

with the Pan-African Clinical Trial Registry (Registry ID: PACTR201803003126291). The study was carried from March to August 2018.

This study was carried out on CABG surgery patients at the National Heart Institute, Giza, Egypt. All patients admitted to the National Heart Institute for CABG during the study period were invited to participate if they met the inclusion criteria. The study was conducted with 45 patients who were randomized into laser, exercise and control groups; the three groups were of equal size ($n = 15$ in each group). Measurements were obtained before and after the intervention period, which was 4 weeks. All of the patients were able to receive the same medical and physical rehabilitation programme during the hospitalization period.

All patients in the study had undergone elective CABG surgery involving longitudinal median sternotomy incision and extracorporeal circulation (through a heart-lung machine). The inclusion criteria were as follows: aged between 45 and 65 years; male gender; haemodynamic stability; body mass index (BMI) from 18.5 to 29.9 kg/m²; acute sternal instability. Data on other characteristics are shown in Table 1. The exclusion criteria included previous thoracic surgery; emergency or urgent coronary artery bypass surgery; respiratory insufficiency after surgery, manifesting hypoxemia with partial oxygen pressure in arterial blood < 60 mmHg [17]; renal insufficiency with serum creatinine ≥ 1.8 mg/dl after surgery [17]; low cardiac output syndrome with ST segment elevation in multiple electrocardiogram leads, cardiac arrhythmias or hypotension, according to the American College of Cardiology Foundation and American Heart Association [18]; other medical conditions, such as diabetes, uncontrolled hypertension and obesity; and previous medical history including conditions that may have influenced the provision of physiotherapy interventions, such as severe asthma, chronic airflow limitation, bronchiectasis, ankylosing spondylitis or lumbar disc prolapse.

Power analysis

Sample size was determined a priori using G*Power (version 3.1.9.2). The calculation was based on the F-test and the

Table 1 Characteristics of patients at baseline

Characteristic	Patients		
	Laser	Exercise	Control
Smoking	12 (80%)	13 (87%)	11 (73%)
Internal mammary artery grafting	1 (7%)	1 (7%)	2 (13%)
Internal mammary artery with unilateral saphenous vein grafting	12 (80%)	13 (87%)	11 (73%)
Internal mammary artery with bilateral saphenous vein grafting	2 (13%)	1 (7%)	2 (13%)
Patients stay more than 2 days in ICU	3 (20%)	4 (27%)	6 (40%)

type-I error rate was set at 5% (alpha level: 0.05). Meanwhile, the effect size of 0.427976 of the main outcome variable (sternal separation, lower level) was obtained from a pilot study performed on three patients from each group, while the type-II error rate was set at 80% power. Considering a 15% dropout rate, the appropriate minimum sample size for this study was 45 patients.

Assessment of eligibility

Fifty-two male patients were recruited to participate in the study. During assessment for eligibility, seven patients were excluded because four of them refused to participate in the study and the other three had post-operative sternotomy healing complications (Fig. 1). Allocation was concealed using sealed opaque envelopes.

Outcome measures

Sternal separation measurement

An ultrasound unit (Siemens, KT-LM200HDS, Korea) was used to measure the transverse sternal separation between the two halves of the sternum at three different levels (upper,

mid and lower) in the supine lying position with the head of the treatment bed inclined at 30° [19–21]. The projected images were used to measure this separation in millimetres.

Median sternotomy photographic analysis

Clinically, sternotomy healing was analysed via photographs using a digital camera (FUJIFILM, 9TJ46864, China) in order to examine hyperaemia and wound closure using the following grading methods: hyperaemia scores: 0 = normal (a colour that closely resembles the colour of the rest of the body), 1 = pink, 2 = red, and 3 = purple; wound closure scores: 0 = total closure, 1 = minor bleeding, 2 = minor dehiscence, and 3 = complete dehiscence. According to these previous scores, the patient's sternotomy healing total score was from 0 (normal skin) to 6 (the worst scar aspect) [17].

Pain assessment

Pain was measured during task performance using a 100-mm visual analogue scale (VAS) ranging from 0 (no pain at all) to 10 (maximal pain) [22]. The tasks performed by the patients included: rotating the trunk, swinging the arms when walking, sitting to standing, supine to sitting, suddenly losing footing, coughing, and reaching above shoulder height [16]. A higher score on the VAS meant higher pain intensity.

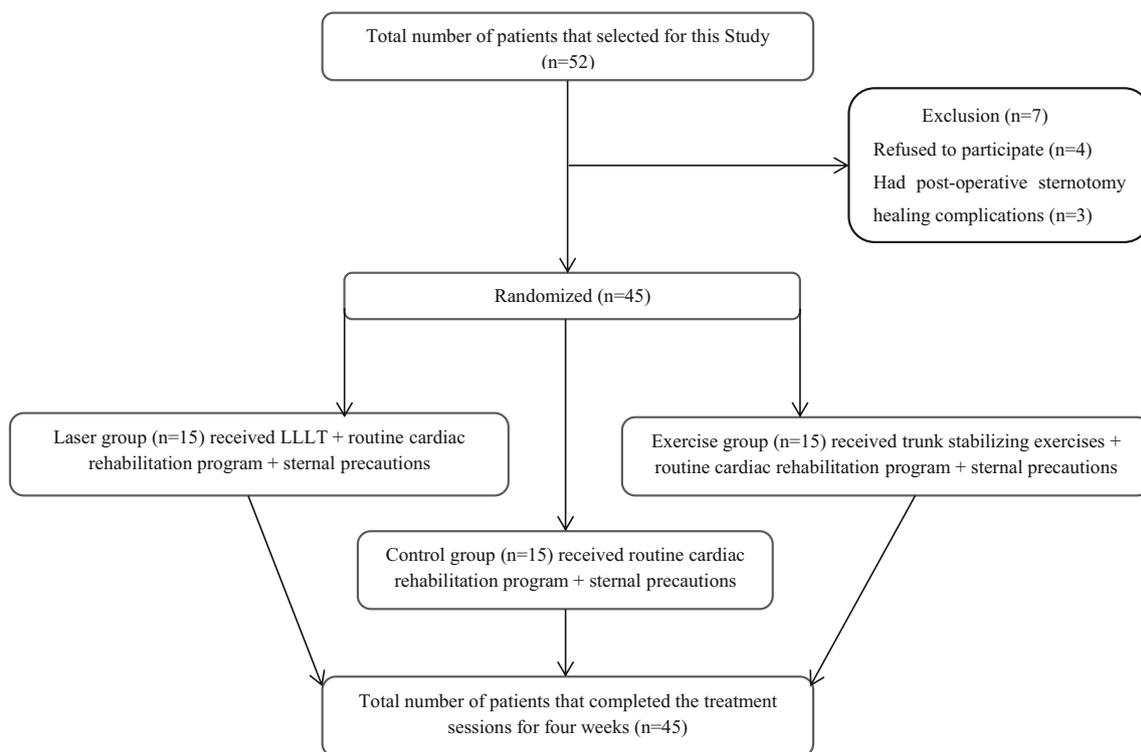


Fig. 1 Flow diagram of the study

Activities of daily living

Functional status was measured using the ADL performance scale through interviews with the patient and a family member as well as medical care staff [23]. The ADL performance scale includes 10 activities, which are: eating meal on one's own, dressing on one's own, going to the toilet on one's own, taking medicine on one's own, walking around in the service on one's own, taking a bath on one's own, reading a newspaper/book on one's own, communicating with other patients on one's own, not having a sleeping disorder, and having the capacity to be discharged. Each activity has a score of 0 or 1 and the scale ranges from 0 (worst ADL performance) to 10 (maximal ADL performance).

Intervention

Low-level laser therapy

A probe laser device (Petra, Laserklasse 2 M, Germany) was used to irradiate the median sternotomy site. In line with Fernandes et al. (2016), the equipment characteristics and irradiation parameters are described in Table 2. The probe laser device was applied at spots along the median sternotomy site, at a distance of 2 cm from each other, for a total of five to eight points. During irradiation, the probe laser device was placed in a perpendicular position to the sternum and in contact with the skin to irradiate each spot for 60 s for a total session time of 5–10 min. Each patient received one session daily, three times a week, for four consecutive weeks [17].

Table 2 Parameters of the instrument used for laser irradiation

Parameters	Values
Energy density (J/cm ²)	6
Energy (J)	2.4
Power (W)	0.04
Spot diameter (cm)	0.5
Spot size (cm ²)	0.4
Time of irradiation (s)	60
Power density (W/cm ²)	0.1
Treatment time per point (s)	60
Number of spots	8
Spatial average energy fluency (SAEF) ^a	0.24
Wavelength	660 nm

^a SAEF = power output × time treatment per point × point numbers/total treated area

Trunk stabilization exercises

Each patient performed trunk stabilization exercises, repeating each one five to ten times, during one session per day, three times a week, for four consecutive weeks. According to El-Ansary et al. (2007) who conducted a study to relate pain with upper limb movement in patients with chronic sternal instability following cardiac surgery, the amount of sternal separation is not related to the type of upper limb activity; however, both unilateral and unilateral-loaded upper limb movements were found to be significantly associated with more sternal pain than bilateral movements [21]. Accordingly, the trunk stabilization exercises were introduced to patients in the sequence associated with this concept.

Routine cardiac rehabilitation programme

According to the recommendations of the American College of Sports Medicine, patients performed aerobic exercises for 20–60 min per session, three to five times per week. Heart rate was monitored during the training session using ECG telemetry. Pain-relieving modalities, such as infrared irradiation, were applied to relieve upper trapezius muscle spasm. Deep breathing exercises were conducted using a volumetric incentive spirometer, in addition to performing huffing and coughing techniques with incisional site support [24].

Statistical analysis

The data were analysed using SPSS Version 19 for Windows (IBM SPSS, Chicago, IL, USA). Descriptive statistics and ANOVA testing were applied to compare the mean age, weight, height and BMI of the three groups. Two-way mixed MANOVA testing was conducted to compare the effect of time (pre versus post) and the effect of treatment (between groups), as well as the interaction between time and treatment on mean values of sternal separation, total sternotomy photography score, VAS score and total ADL score between the three groups. The level of significance for all statistical tests was set at $P < 0.05$.

Results

Forty-five patients completed the study, and their anthropometric characteristics are described in Table 3. There were no significant differences between the three groups in terms of mean age, weight, height, and BMI ($P > 0.05$).

There was a significant main effect of treatment and time ($P < 0.05$). There was also a significant interaction effect of

Table 3 Anthropometric characteristics of patients

	Laser group $\bar{X} \pm \text{SD}$	Exercise group $\bar{X} \pm \text{SD}$	Control group $\bar{X} \pm \text{SD}$	<i>P</i> value
Age (years)	52.8 ± 3.29	53.73 ± 6.39	55.73 ± 3.63	0.22
Weight (kg)	83.06 ± 9.69	82.46 ± 5.62	85.73 ± 6.93	0.46
Height (cm)	176.2 ± 7.69	172.06 ± 6.54	175.26 ± 5.14	0.2
BMI (kg/m ²)	26.68 ± 1.58	27.87 ± 1.63	27.91 ± 2.08	0.11

\bar{X} , mean; SD, standard deviation; *P* value, probability value

treatment and time ($P < 0.05$). The mean pre- and post-values, standard deviation (SD), percentage of change and *P* value of sternal separation, total sternotomy photography score, VAS score, and total ADL score of the groups are shown in Table 4.

Sternal separation

The upper-sternal separation results revealed that there was a statistically significant decrease in the mean value of

post-laser treatment compared with pre-treatment ($P < 0.05$), while both the exercise and the control groups showed a non-significant decrease ($P > 0.05$) (Fig. 2). For between-groups comparison, the post hoc test revealed that there were no significant differences between the pre-values of the laser and control, laser and exercise and exercise and control groups ($P = 1, 1, 0.98$, respectively), while the post-values showed a significant difference between the laser and control groups ($P = 0.04$), but there

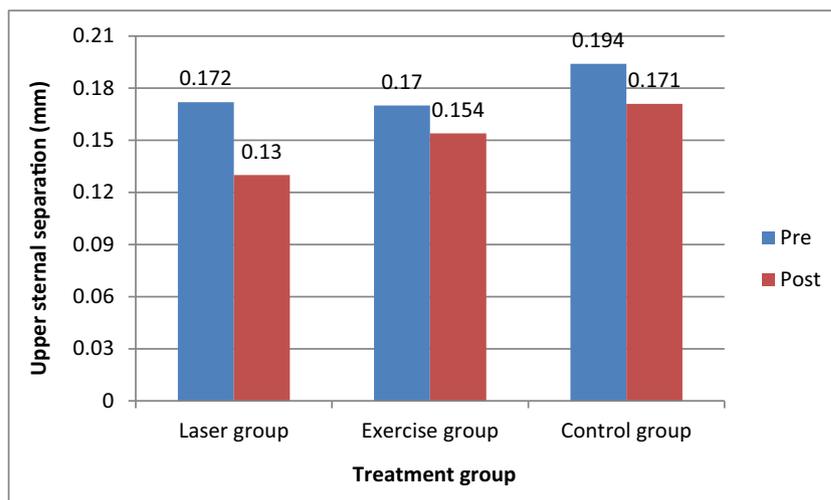
Table 4 Pre- and post-mean values, standard deviation (SD), percent of change and *P* value of the three group variables

Variables			Laser group	Exercise group	Control group
Sternal separation	Upper level	Pre-treatment $\bar{X} \pm \text{SD}$	0.172 ± 0.07	0.17 ± 0.04	0.194 ± 0.06
		Post-treatment $\bar{X} \pm \text{SD}$	0.13 ± 0.03	0.154 ± 0.04	0.171 ± 0.05
		Percent of change	24.41%	9.41%	11.85%
		<i>P</i> value	0.002*	0.22	0.08
	Mid-level	Pre-treatment $\bar{X} \pm \text{SD}$	0.199 ± 0.1	0.232 ± 0.05	0.218 ± 0.08
		Post-treatment $\bar{X} \pm \text{SD}$	0.155 ± 0.06	0.187 ± 0.04	0.2 ± 0.05
		Percent of change	22.11%	19.39%	8.25%
		<i>P</i> value	0.01*	0.009*	0.33
	Lower level	Pre-treatment $\bar{X} \pm \text{SD}$	0.238 ± 0.12	0.3 ± 0.1	0.263 ± 0.12
		Post-treatment $\bar{X} \pm \text{SD}$	0.2 ± 0.11	0.242 ± 0.08	0.258 ± 0.08
		Percent of change	15.96%	19.33%	1.9%
		<i>P</i> value	0.07	0.001*	0.79
Total sternotomy photography score	Pre-treatment $\bar{X} \pm \text{SD}$	2.86 ± 0.74	2.93 ± 1.03	3.2 ± 1.14	
	Post-treatment $\bar{X} \pm \text{SD}$	0.93 ± 0.7	1.66 ± 1.04	2.53 ± 1.3	
	Percent of change	67.48%	43.34%	20.93%	
	<i>P</i> value	0.0001*	0.0001*	0.002*	
VAS	Pre-treatment $\bar{X} \pm \text{SD}$	87.06 ± 5.76	84.92 ± 7.17	83.9 ± 6.73	
	Post-treatment $\bar{X} \pm \text{SD}$	12.17 ± 4.34	16.63 ± 3.82	32.88 ± 8.61	
	Percent of change	86.02%	80.41%	60.81%	
	<i>P</i> value	0.0001*	0.0001*	0.0001*	
Total ADL	Pre-treatment $\bar{X} \pm \text{SD}$	2.86 ± 0.99	2.8 ± 1.32	2.6 ± 1.29	
	Post-treatment $\bar{X} \pm \text{SD}$	9.4 ± 0.63	9.26 ± 0.45	6.26 ± 1.16	
	Percent of change	228.67%	230.71%	140.76%	
	<i>P</i> value	0.0001*	0.0001*	0.0001*	

\bar{X} , mean; SD, standard deviation; *P* value, probability value

*There were statistically significant differences between the three groups ($P < 0.05$)

Fig. 2 Mean values of upper sternal separation for the three groups



were no significant differences between the laser and exercise groups and between the exercise and control groups ($P = 0.42, 0.9$, respectively).

The mid-sternal separation results revealed that there was a statistically significant decrease in the mean values of both post-laser and post-exercise treatment ($P < 0.05$) compared with pre-treatment, while the control group showed a non-significant decrease ($P > 0.05$). The post hoc test revealed no significant differences between the pre-values of the three groups ($P = 1, 0.84, 1$, respectively), while the post-values also showed no significant differences ($P = 0.07, 0.37, 1$, respectively).

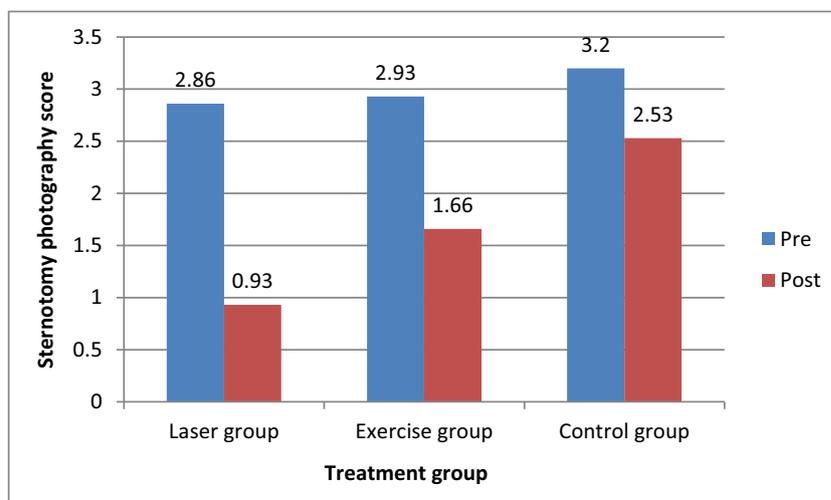
The lower-sternal separation results showed that there was a statistically significant decrease in the mean value of post-exercise treatment compared with pre-treatment ($P < 0.05$), while both the laser and control groups showed a non-significant decrease ($P > 0.05$). The post hoc test revealed that there were no significant differences between the pre-values of

the three groups ($P = 1, 0.44, 1$, respectively), while the post-values also showed no significant differences ($P = 0.4, 0.88, 1$, respectively).

Sternotomy photography score

The results revealed that there was a statistically significant decrease in the mean post-treatment values compared with pre-treatment for the laser, exercise and control groups ($P < 0.05$) (Fig. 3). For between-groups comparison, the post hoc test revealed that there were no significant differences between the pre-values of the three groups ($P = 1, 1, 1$, respectively), while the post-values showed a significant difference between the post-values of the laser and control groups ($P = 0.0001$). However, there were no significant differences between the laser and exercise groups and between the exercise and control groups ($P = 0.18, 0.08$, respectively).

Fig. 3 Mean values of total sternotomy photography score for the three groups



Visual analogue scale

The results revealed that there was statistically significant decrease in the mean post-treatment values compared with pre-treatment of laser, exercise, and control groups ($P < 0.05$) (Fig. 4). Post hoc test revealed that there were no significant differences between pre-values of the three groups ($P = 0.58, 1, 1$, respectively) while post-values showed significant differences between post-values of laser and control groups and between exercise and control groups ($P = 0.0001, 0.0001$, respectively) but there was no significant difference between laser and exercise groups ($P = 0.14$).

Activities of daily life

The results revealed that there was a statistically significant decrease in the mean post-treatment values compared with pre-treatment for the laser, exercise, and control groups ($P < 0.05$) (Fig. 5). The post hoc test revealed that there were no significant differences between the pre-values of the three groups ($P = 1, 1, 1$, respectively), while the post-values showed significant differences between the laser and control groups and between the exercise and control groups ($P = 0.0001, 0.0001$, respectively); but there was no significant difference between the laser and exercise groups ($P = 1$).

Discussion

This randomized controlled trial is the first trial to investigate the effect of LLLT versus trunk stabilization exercises on sternotomy healing following CABG surgery. The results of the present study showed improvements in all three groups for all measured variables, with superior performance offered by

LLLT. LLLT was more efficacious than trunk stabilization exercises in decreasing sternal separation, in addition to decreasing pain and increasing ADL performance. Consequently, this led to faster sternotomy healing for those patients who had undergone CABG surgery and experienced sternal instability, helping them to rapidly return to their normal ADL and regain independence in their community as well.

Inflammatory cells play an important role in the healing process. As increased inflammatory cells inhibit the wound healing process, depletion of these cells hastens healing. Low-energy (e. g., 1 and 5 J/cm²) laser irradiation suppresses inflammation and boosts the growth phase in which collagen fibres are synthesised, which results in tissue strengthening [25]. LLLT has a potent impact in changing cellular functions by improving the activity of the mitochondrial respiratory chain in which cytochrome oxidase and ATP production are increased [26], as well as effectively stimulate local vasculogenesis, which hastens bone formation [27] and alters collagen fibre arrangements [28]. LLLT and tissue interaction change the mechanics of the cell micro-environment, thus improving its activity [29]. Khoo et al. (2014), who concluded that LLLT after CABG surgery could decrease cardiac cell damage and accelerate cardiac tissue repair, recommended laser therapy as a promising intervention for improving prognosis after CABG surgery [30]. Application of laser therapy at the fracture site accelerates the bone repair process, especially the early stages of bone remodelling, by increasing callus volume and BMD. LLLT also increases new bone formation in osteopaenic rats and augments bone strength, calcium content and BMD [31]. LLLT increases the activity of osteoblast-like cells [32], the synthesis of DNA and RNA, the formation of bone nodules [13], the activity of ALP, and the expressions of osteopontin and collagen

Fig. 4 Mean values of VAS score for the three groups

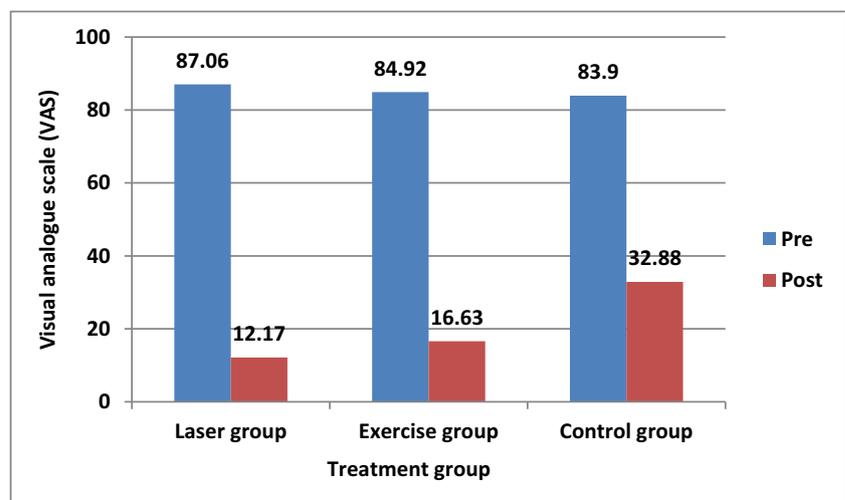
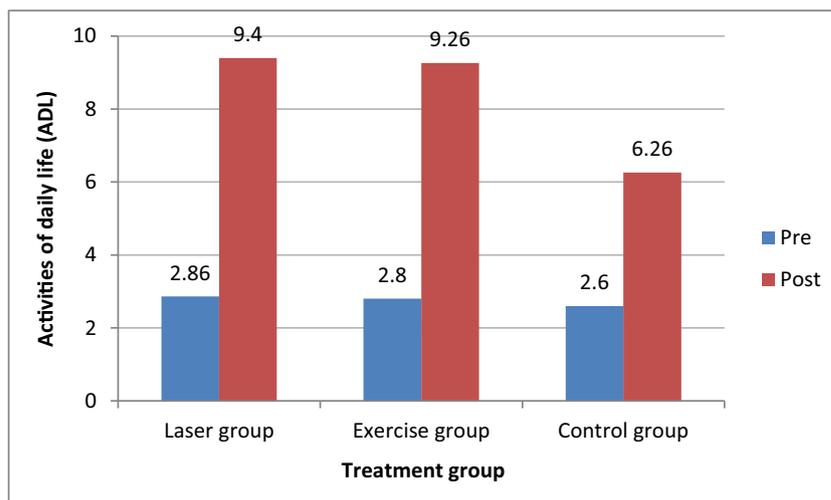


Fig. 5 Mean values of total ADL score for the three groups



type-I mRNA [33]. All previously stated mechanisms favour the beneficial effect of LLLT in improving sternotomy healing in CABG surgery patients with median sternotomy.

The results of this study are in line with those reported by Baptista and colleagues (2009), who examined the effect of LLLT on the prevention of sternotomy dehiscence in 40 patients. Their results indicated that patients in the LLLT-irradiated group had a 500% better sternotomy healing status than in the placebo group. This outcome calls for the application of LLLT immediately following surgery during the initial inflammatory phase so as to be an effective prophylactic therapy [34]. In a single-case study, Dixit and colleagues (2013) investigated the probable impact of LLLT on delayed wound healing and pain in a diabetic patient with chronic dehiscent sternotomy after CABG. They performed measures in relation to wound photography, the wound area, the pressure ulcer scale for healing (PUSH), and the VAS for pain. The results showed a decrease in the PUSH score for a dehiscent sternum, as well as a decrease in the VAS score for bilateral shoulders and a dehiscent sternum [35]. LLLT decreases pain [36] and accelerates sternotomy healing early on following CABG surgery [37]. These studies reinforce the value of our current work, in that we recommend the use of LLLT in the early post-operative period for patients who have undergone median sternotomy as a prophylactic strategy to prevent sternal wound healing complications and decrease pain perception, thus decreasing both the physical and psychological burdens of those patients.

The results of our study are also consistent with those of Fernandes et al. (2016), who reported the efficacy of LLLT ($\lambda = 660$ nm) with regard to sternotomy healing in patients who had undergone CABG surgery. The measured outcomes were hyperaemia and wound closure scores. The patients who received LLLT showed a significant improvement in hyperaemia and wound closure scores, while their sternotomy

incisions demonstrated less hyperaemia, incisional bleeding and dehiscence [17].

On the other hand, a number of studies have confirmed the effect of trunk stabilization exercises on sternotomy healing. One such study presented a biomechanical model, which interprets the bracing effect of the anterior trunk muscles, which are oriented in the transverse direction. Hence, the sacroiliac joint (SIJ) in the lower trunk is efficiently locked [38–40]. It has also been proposed that contraction of these transversely oriented muscles, such as the transverse abdominis, creates forces that result in a ‘corset-like’ action, which effectively reduces SIJ laxity and ensures its stability [38–40]. Trunk stabilization exercises train the muscles with a transverse orientation, such as the transverse abdominis acting perpendicularly to the sagittal plane, in which the sternotomy incision during CABG surgery lies in a similar direction to the sacroiliac joint, in turn ensuring trunk stability, especially the divided sternum, and reducing sternal motion and separation. Therefore, training these muscles approximates to the production of sternal stability by the sternal halves in the coronal and transverse planes during trunk movement, thus reducing excessive sternal motion [16].

The current study has some limitations. It is a single-centre trial with a small sample size. Therefore, we recommend replicating the study with a larger sample size in multiple centres.

Conclusion

Both LLLT and stabilization exercises are potent physiotherapy modalities, providing better sternotomy healing for patients who have undergone CABG surgery, compared with routine cardiac rehabilitation programmes, with superior performance in the case of LLLT at the upper sternum and trunk stabilization exercises for the lower sternum. This finding

calls for a further study to investigate the combined effects of both LLLT and trunk stabilization exercises on sternotomy healing for a longer duration than 4 weeks, as well as their impact on decreasing pain and improving ADL performance.

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Compliance with ethical standards

Conflicts of interest The authors declare that they have no conflicts of interest.

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