



## Impact of a Physical Reconditioning Program on the Quality of Life of Patients Following Coronary Artery Bypass, with or without Led Therapy: Preliminary Results

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### **Authors' contributions**

*This work was carried out in collaboration between all authors. Authors RAO and RAN designed the study, performed the statistical analysis, the analyses of the study, and wrote the first draft of the manuscript. Authors GAF and ACGL wrote the protocol, and managed the clinical procedures. Author RBAJ managed the surgery procedures. All authors read and approved the final manuscript.*

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### **ABSTRACT**

**Aims:** Analyse the impact of a physical recondition program (PRP) on Quality of Life (QOL), associated or not to LED therapy on sternotomy after coronary-artery bypass graft (CABG).

**Study Design:** Follow-up after a clinical trial.

**Place and Duration of Study:** Participants were recruited and followed-up from September 2011 to March 2012 in Teresina, Piauí, Brazil.

**Methodology:** 90 volunteers were electively submitted to CABG. During hospitalization, volunteers were randomly allocated into three different groups of equal size: Light emitting diode (LED:  $\lambda$  of  $640 \pm 20$  nm, SAEF of  $1.2$  J/cm<sup>2</sup>), placebo and control. All patients were subjected to a physical therapy program during their hospitalization and

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then stimulated to join a physical therapist-supervised PRP after discharge. The patients were followed for six months after the surgery. The Short-Form (36) was used to assess QOL.

**Results:** After six months, patients' QOL had increased significantly in all aspects when compared to pre-operative scores, regardless the use of LED (Mann-Whitney test  $p \leq 0.05$ ).

**Discussion:** While the use of LEDs has shown to have analgesic and healing effects during hospitalization, the photobiomodulator not proved to be important in the QOL perception, six months after discharge. In addition, Short-Form (36) showed to be a useful tool to assess the quality of life after CABG, collaborating with risk estimation and prognosis.

**Conclusion:** The QOL of the patients who adhered to a physical reconditioning program supervised by a physical therapist increased in the first six months after surgery, while those patients who also were submitted to LED therapy during hospitalization had even better results.

*Keywords: Coronary-artery bypass grafting; light emitting diode; sternotomy; quality of life; physical therapy.*

## 1. INTRODUCTION

Cardiovascular disease is the number one cause of death globally, according to the World Health Organization (WHO), being the most important cause of death. In 2011, heart diseases were responsible for 596,339 deaths in United States, followed by cancer (575,313) and chronic lower respiratory diseases (143,382). For this reason, public health efforts to improve lifestyles, controlling lifestyle-related major cardiovascular risk factors, will certainly contribute to cardiovascular disease prevention [1]. One of the most widely used therapeutic modality in the treatment of atherosclerotic coronary artery disease is the Coronary-artery bypass grafting (CABG). The Brazilian Health System (SUS) is one of the world's largest health care systems; from 2005 to 2007, more than 63,000 CABG surgeries were conducted in Brazil, representing approximately 340 surgeries per million inhabitants. The mortality rate in Brazil for this type of surgery is approximately 6.2% [2], which is significantly higher than in developed countries such as Canada (5.76%) [3] and the United States (3.05%) [4]. The high prevalence of cardiovascular risk factors among patients undergoing CABG in Brazil likely accounts for the high rate of post-operative mortality in its population.

Deep surgical wound dehiscence and infections of the median sternotomy are some of the problems that can greatly increase post-operative morbidity and mortality. Mediastinitis occurs in 0.4% to 5% of the surgeries, and even with existing early diagnosis and different treatment modalities, it is still a serious complication once the mortality numbers reach between 14% and 47% [5]. Thus, an important issue is the development of strategies and of new therapeutic modalities that can reduce these levels of post operative mortality.

Light emitting diode (LED) devices are systems that produce monochromatic and clean light when energized. The device temperature increase that occurs during its operation is insignificant, and their low cost and convenience are causing LED devices to conquer the market. They have also been increasingly tested and studied in terms of their therapeutic properties [5-7]. Although this type of light is present in many electronic components used in our daily lives, its use as a photobiomodulator is recent [8,9]. With the introduction of LED

therapy, several debates have been generated about differences from and similarities to lasers but, in both methods, there is not an appropriate protocol of irradiation parameters yet, including wavelength and energy density, motivating further investigation in this field. Some laboratorial and clinical studies have reported that LED therapy shows a wide variety of effects, including pain relief with LED at  $\lambda$  626 nm and  $2.5 \text{ J/cm}^2$  [11], and inflammation reduction [10] with LED at  $\lambda$  640 nm and  $6 \text{ J/cm}^2$ . A previous study about the mechanical resistance and healing of *Rattus norvegicus* chest incision after being irradiated with LED at  $\lambda$  640 nm,  $6 \text{ J/cm}^2$  and  $10 \text{ J/cm}^2$  showed a better result at  $6 \text{ J/cm}^2$  [10]. In addition, Oliveira et al. [12] conducted a trial with 90 volunteers subjected to CABG with longitudinal sternotomy and LED post operative irradiation and evidenced a pain reduction and a fast end better sternotomy incision healing, with dehiscence incidence reduction. These studies suggest a possibly a positive impact in patient recover after surgery.

The LED has aided the development of technological systems of light production and emission and is a hopeful alternative for the low-intensity lasers currently used in tissue repair therapy [13]. LED therapy and low-intensity laser therapy (LILT) at infrared wavelengths and energy density around  $2.5 \text{ J/cm}^2$  to  $10 \text{ J/cm}^2$ , or even more, have been used to irradiate surgical incisions, accelerating postoperative recovery. Specifically, these treatments reduce pain and quicken incision healing, which is particularly important in CABG due the possibility of sternal incision dehiscence. Thus, LED therapy could reduce patient mortality. These therapeutic effects can have a positive impact on the Quality of Life (QOL) of patients subjected to CABG, once can reduce dehiscence incidence, local pain and inflammation, accelerating the recovery period.

In general, the physical and emotional consequences of a chronic illness, such as coronary artery diseases (CAD), influence QOL [14]. Many patients with CAD are subjected to CABG and certain side effects of the surgery such as difficulty sleeping, pains or limited physical mobility, which appear or worsen at post operative period, can affect the quality of life (QOL) of the patients and are not taken into account in traditional evaluations [15]. It is also important that, after surgery, CABG patients join a physical therapist-supervised physical reconditioning program (PRP), which includes respiratory exercises and aerobic activities three times a week for at least six months. This type of program leads to functional improvement and increased QOL [12].

This study aimed to analyse the Quality of Life (QOL) impact of a physical therapist-supervised physical recondition program (PRP) associated or not to LED therapy on chest incision at  $\lambda$  640 nm and  $6 \text{ J/cm}^2$  in patients who underwent CABG.

## **2. MATERIALS AND METHODS**

The study was carried out in a private hospital that performs cardiac surgery for the Brazilian public health system. The hospital is a regional reference center for this type of surgery, serving an area of over 6 million inhabitants. The participants were recruited between September 2011 and March 2012, and they were followed until October 2012. All patients admitted to the hospital during the study period were invited to participate, attending the indication for CABG and the inclusion criteria. The study was conducted with 90 volunteers who were randomly allocated into three different groups of equal size. All of the subjects signed a written declaration of informed consent for LED therapy and the follow-up, and their rights were protected. The protocol for this study was approved by the local research ethics committee and registered at the Brazilian Clinical Trial Registry and the International Clinical

Trials Registry Platform of the World Health Organization under RBR-38wgx6 and Universal Trial Number U1111-1128-9666, respectively.

Randomization and blind procedures, consisted of simply drawing cards marked 1, 2 or 3, where 1 meant the LED group, 2 meant the placebo group, and 3 meant the control group. The drawing was performed during the patient's hospital admission, which always occurred at least 24 hours before the surgery. The researchers were previously trained and divided into therapists and evaluators. The therapists were assistants responsible for conducting the therapy and registering the procedures, and the evaluators were responsible for assessing the patients and their results. Each patient was identified by a code registered by one of the therapist researchers, who ensured that the evaluating researchers were blinded to the code until the final statistical analysis was performed. The patients were blinded to the study by the use of opaque goggles during the LED irradiation.

The inclusion criteria were: individuals with clinical indication and subjected to elective coronary artery bypass surgery with a longitudinal sternotomy incision, both gender and ages under 75 years. The clinical indication was evidenced by clinical symptoms and signs followed by ischemia signs detected by ergometric test or coronary catheterization. Exclusion criteria consisted of morbid obesity, previous thoracic surgery, emergency or urgent coronary artery bypass surgery, respiratory or renal insufficiency after surgery, low cardiac output syndrome, clinical complications that demanded changes in analgesic protocols and any other post-surgery complications. Individuals who could not be monitored during the first six months after the operation were also excluded.

The employed analgesic protocol was the one routinely set by the hospital that consisted of tramadol hydrochloride and dipyrone administered intravenously on a fixed 6 h schedule. Morphine sulfate was administered on an as-needed basis. Those patients who needed doses of morphine were excluded from the study. A pre-operative assessment consisted of an explanation of the procedures, the inclusion and exclusion criteria certification, a submission of the Short-Form (36) for the QOL analysis, and the group drawing.

The experimental group was subjected to LED irradiation immediately after surgery and on subsequent days 2, 4, 6 and 8. The irradiation was performed at spots alongside the incision 2 cm from each other, perpendicularly and in contact to the skin, for a total of 8 points. A translucent film protected the LED probe. The equipment characteristics and irradiation parameters are described in Table 1. The placebo group was subjected to the LED application process but with the equipment turned off. The control group was only subjected to the assessment protocols and the follow-up. During the hospitalization period, consisting in seven days at all, all patients were subjected to a physical therapy program including respiratory exercises for expectoration and lung ventilation improvement, limb movements and low-impact physical activities. A well-designed control condition is an essential component of a clinical trial to foster the unambiguous interpretation of study findings. So, it is important to avoid the "placebo effect" with a control group [16].

The outcomes assessed were patient's adherence to the PRP and the quality of life (QOL) in the first six months after surgery. The patients were encouraged to join a physical therapist-supervised PRP, which consisted of respiratory exercises and aerobic activities three times a week for at least six months. During the first month, respiratory exercises and low-intensity physical exercises such as walking short distances were included, and aerobic exercises were added in the next two months. The Short-Form (36) was applied on the day before the operation and at one and six months post-surgery. Patient participation in a PRP was

ascertained by regular contact with the physical therapist responsible for the program. The incidence of sternum dehiscence was also evaluated during this period.

**Table 1. LED equipment characteristics and irradiation parameters**

Equipment	Microdont® portable equipment, São Paulo, Brazil
Application mode	Stationary probe 90° perpendicular to and in contact with the incision surface
Wavelength	640±20 nm
Power output	70 mW
Spot size	1.77 cm <sup>2</sup>
Spot diameter	1.5 cm
Power density	0.039 W/cm <sup>2</sup>
Energy density per point	6 J/cm <sup>2</sup>
Treatment time per point	152 s
Number of spots	8
Spatial average energy fluency (SAEF)*	1.2 J/cm <sup>2</sup>

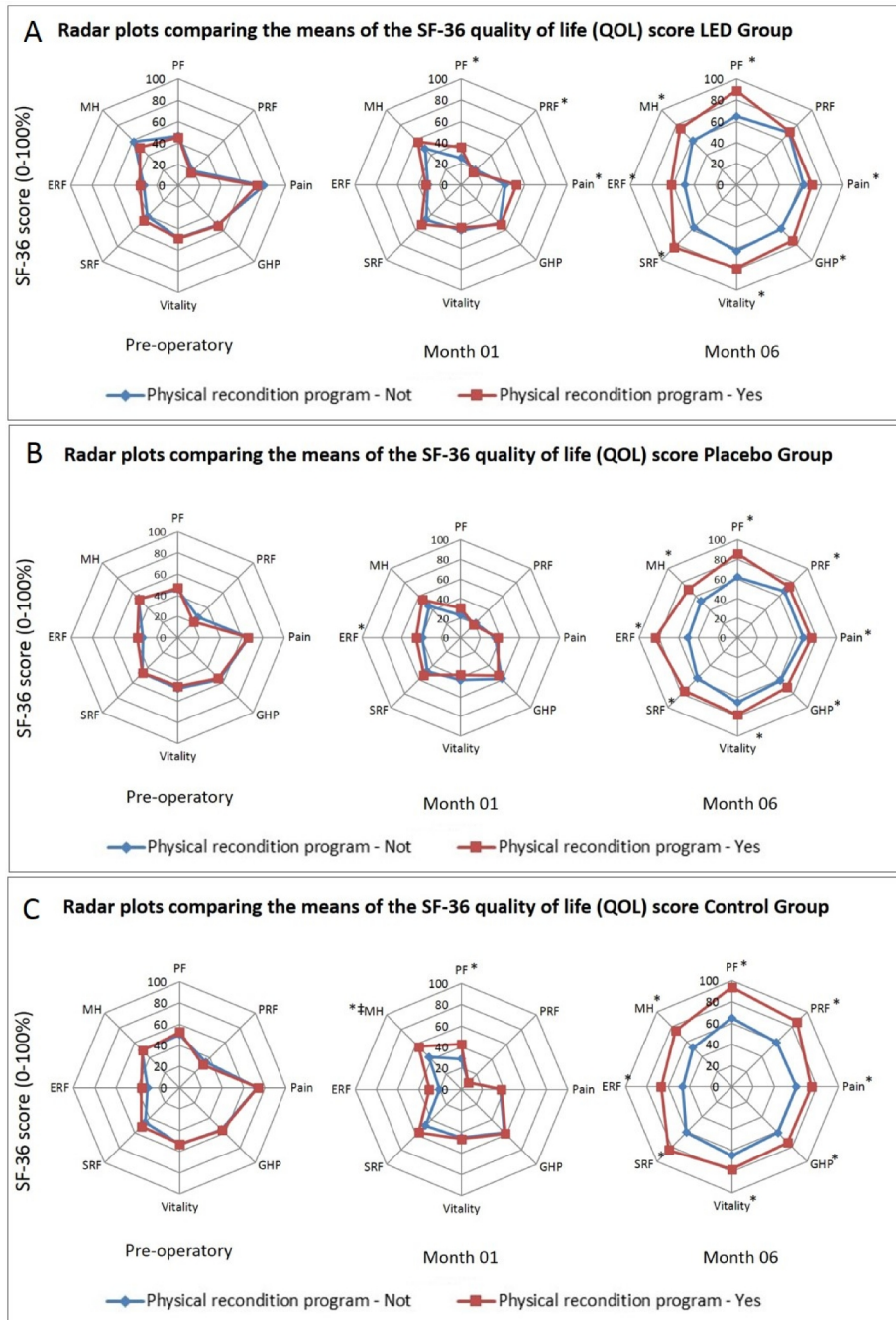
The results were evaluated using the software Statistica 7.0 StatSoft®. Intragroup QOL aspects were evaluated by the Mann-Whitney test, and intergroup QOL aspects were evaluated by ANOVA and Tukey HSD post hoc tests. All significance levels were set at p≤0.05.

### 3. RESULTS

Initially, 93 patients were selected for the study, but three were excluded due to post-surgical complications. Ninety individuals were followed for six months after their surgeries, and during this period, three additional individuals (one from the placebo group and two from the control group) were excluded due to sternotomy dehiscence. The participants' demographics characteristics are described in Table 2. No significant difference in the age, body mass index (BMI) or incision length was found among the groups, although there was a major prevalence of males (Kruskal-Wallis test ≥0.05 for age, weight, height, BMI and incision length. Fisher exact test for gender p≤0.05)).

**Table 2. Participants' baseline demographics and other baseline characteristics**

Gender	Group					
	Placebo		Control		LED	
	N (%)	Mean±SD	N (%)	Mean±SD	N (%)	Mean±SD
Female	10(33.3%)		11(36.7%)		14 (46.7%)	
Male	20(66.7%)		19 (63.3%)		16 (53.3%)	
Age (years)		59.0±8,8		60.2±10		60.6±8.7
Weight (kg)		63.3±8,9		64.66±10		61.5±8.4
Height (m)		1.6±0.1		1.6±0.1		1.6±0.1
BMI (kg/m <sup>2</sup> )		25.2±3		25.42±2.5		25.0±3.0
Incision length (cm)		19.8±0.5		19.60±1.9		19.9±0.4



**Fig. 1. Radar plots comparing the means of the Short-Form (36) quality of life (QOL) score of LED (A), Placebo (B) and Control (C) groups**

QOL scores were determined during the pre-operation procedure as well as 1 and 6 months after surgery. The patients were divided into subgroups based on whether they joined a physical reconditioning program (PRP). Legend: PF-Physical functioning, PRF-Physical role functioning, GHP-General health perception, SRF-Social role functioning, ERF-Emotional role functioning, MH-Mental health. \*2-tailed  $p \leq 0.05$ , Mann-Whitney test comparing who joined a PRP and not

Participants QOL was assessed during the pre-operation procedure as well as 1 and 6 months after the operation. Patients were also encouraged to join a PRP for post-surgery patients, although most of them had no access to this type of treatment because they lived in small cities distant from such physical therapist-run programs. This difficulty was reported by 36 (66.7%) individuals as the main cause of having not joined a PRP, followed by economic restrictions (15, or 27.8%), and while three people (5.6%) reported other reasons. In the LED group, 12 (40%) joined a PRP, and 18 (60%) did not; in the placebo group, 12 (40.0%) joined a PRP, 17 (56.7%) did not, and one (3.3%) was excluded due to dehiscence; and in the control group, 9 (30.0%) joined a PRP, 19 (63.3%) did not, and two (6.7%) were excluded due to dehiscence.

The intragroup, intra sub-group and intergroup results were analyzed, and the Short-Form (36) scores were compared between those patients who did and did not join a PRP. Those results are presented in Fig. 1(above).

There was an improvement in Short-Form (36) scores in all groups in all aspects six months after surgery (Mann-Whitney test  $p \leq 0.05$ ), except in PRF in LED group Fig. 1. Table 3 shows SF36 scores in patients submitted to PRP. Kruskal-Wallis test compared the scores in different moments: pre-operative, month 01 and month 06.

**Table 3. Short-Form (36) scores in patients submitted to physical reconditioning program. Kruskal-Wallis test comparing the scores of pre-operative, one month and six months of post operatory**

Group and SF36 aspect		SF36 score (Mean±SD)			p
		Pre-operative	Month 01	Month 06	
LED	Physical Functioning	45.4±7.8	35.4±8.1	88.6±8.8	0.000001
	Physical Role Functioning	16.7±19.5	16.3±11.3	70.8±20.9	0.000001
	Pain	73.3±9.7	52.2±14.5	70.5±6.5	0.000046
	General Health Perception	52.8±8.8	53.1±8.6	74.3±1.6	0.000001
	Vitality	49.2±4.7	40.4±6.6	78.8±6.4	0.000001
	Social Role Functioning	45.8±9.7	53.1±10.8	83.3±8.1	0.000001
	Emotional Role Functioning	2.8±9.6	11.1±16.4	61.7±20.7	0.000003
	Mental Health	56.7±4.5	57.3±7.3	75.3±7.2	0.000001
Placebo	Physical Functioning	47.1±11.8	30.4±17.0	85.83±12.6	0.000001
	Physical Role Functioning	20.8±17.9	10.4±12.9	93.75±15.5	0.000001
	Pain	66.3±7.5	37.7±12.7	74.50±16.7	0.000001
	General Health Perception	53.8±9.9	53.8±9.9	70.58±7.0	0.000036
	Vitality	45.8±7.0	37.5±8.9	78.33±9.4	0.000001
	Social Role Functioning	46.9±10.8	53.1±9.4	76.04±12.5	0.000001
	Emotional Role Functioning	13.9±17.2	50.0±22.5	83.33±17.4	0.000001
	Mental Health	51.3±4.1	55.0±8.4	70.33±8.8	0.000001
Control	Physical Functioning	52.7±8.8	42.7±8.2	93.6±6	0.000001
	Physical Role Functioning	13.6±13.1	9.1±12.6	86.4±17.2	0.000001
	Pain	73.5±6.3	37.6±10	74.9±12.8	0.000001
	General Health Perception	56.4±7.2	58.6±7.9	74.0±6.2	0.000003
	Vitality	52.7±6.1	46.4±7.8	77.7±7.2	0.000001
	Social Role Functioning	51.1±11.8	56.8±10.3	84.1±8.1	0.000001
	Emotional Role Functioning	6.1±13.5	30.3±31.5	66.7±25.8	0.000013
	Mental Health	49.5±6.8	56.7±12.6	74.9±7.2	0.000001

Table 4 shows SF36 scores in patients not submitted to PRP. Kruskal-Wallis test compared the scores in different moments: pre-operative, month 01 and month 06. No statistical differences were observed among LED, placebo and control group, which suggest that LED irradiation has no impact in QOL after CABG (Kruskal-Wallis test  $p \geq 0.05$ ). In other hand, a PRP has a positive improving effect.

**Table 4. SF36 scores in patients NOT submitted to physical reconditioning program. Kruskal-Wallis test comparing the scores of pre-operative, one month and six months of post operatory**

Group and SF36 aspect		SF36 score (Mean±SD)			p
		Pre-operative	Month 01	Month 06	
LED	Physical Functioning	46.7±7.7	25.3±7.6	64.7±10.7	0.000001
	Physical Role Functioning	19.4±16.2	19.4±6.2	69.4±16.2	0.000001
	Pain	75.6±9.4	41.7±12.5	63.2±9.9	0.000001
	General Health Perception	51.4±7.1	51.6±7	58.8±6.7	0.002405
	Vitality	48.9±5.0	43.3±8.7	62.8±5.8	0.000001
	Social Role Functioning	45.8±12.1	46.5±12.7	56.9±13.7	0.020301
	Emotional Role Functioning	1.9±7.9	11.1±16.2	38.9±17.2	0.000001
	Mental Health	56.2±5.0	48.2±5.0	58.4±4.8	0.000001
Placebo	Physical Functioning	45.6±9.8	22.8±8.6	61.9±9.4	0.000001
	Physical Role Functioning	6.9±14.4	1.4±5.9	47.2±14.6	0.000001
	Pain	66.8±4.6	34.9±15.5	56.8±4.6	0.000001
	General Health Perception	55.6±7.4	58.7±9.4	61.2±8.5	0.14857
	Vitality	48.1±8.1	42.8±10.2	65.6±11.1	0.000001
	Social Role Functioning	47.2±11.0	47.9±11.5	57.6±12.2	0.015319
	Emotional Role Functioning	13.0±20.3	38.9±26.2	20.4±28.3	0.009806
	Mental Health	52.2±4.9	45.8±9.6	52.7±5.5	0.007039
Control	Physical Functioning	50.3±5.4	28.7±5.7	65.0±11.4	0.000001
	Physical Role Functioning	9.2±12.4	9.2±12.4	59.2±12.4	0.000001
	Pain	72.7±9.0	36.6±12.4	60.7±10.0	0.000001
	General Health Perception	55.5±5	57.5±5.1	61.0±7.1	0.016686
	Vitality	53.2±5.8	45.0±7.6	64.7±9.8	0.000001
	Social Role Functioning	46.1±10.3	48.0±11.2	60.5±14.0	0.000759
	Emotional Role Functioning	5.3±16.7	10.5±15.9	26.3±23.8	0.003675
	Mental Health	50.1±7.2	43.2±9.3	52.0±6.7	0.002418

Sternotomy dehiscence occurred in one individual in the placebo group and in two of the control group patients. The LED group did not present any case of dehiscence. However, these results were not sufficient to perform a statistical estimation of risks. In all circumstances, the dehiscence occurred at the first month after the operation. Those individuals were excluded once they became unable to be followed-up.

#### 4. DISCUSSION

After an acute event or with chronic heart conditions, patients need structured support to restore their quality of life and to maintain or improve functional capacity. They require counselling to prevent event recurrence by adhering to a medication plan and adopting a healthy lifestyle. Cardiac rehabilitation, including a PRP can be viewed as a clinical application of preventive care for widespread risk reduction and overall long-term care of



cardiac patients. The program is supplemented by a flexible follow-up scheme, and easy access to specialized professionals. Consequently, PRP is a Class I recommended recommendation by the European Society of Cardiology [16,17], American Heart Association, American College of Cardiology [18], and Brazilian Heart Association recommend, at least, a 6 months follow-up program [19].

Physical Rehabilitation based on aerobic exercises is associated with improvements in blood pressure regulation, lipid profile, abdominal fat reduction, insulin sensitivity, and hemodynamic inflammatory and psychosocial parameters [20]. The mechanisms by which aerobic exercise training in general improves blood pressure may be by influencing Nitric oxide (NO) production. Regular exercise has been shown to significantly decrease the concentration of plasma endothelin-1 (ET-1), a powerful vasoconstrictor peptide produced by vascular endothelial cells, which might contribute to the increased production of NO [21]. Additionally, the increased NO production may be due to increased blood flow velocity induced by exercise. Moreover, aerobic training improves glucose control and insulin sensitivity reducing both visceral and sub-cutaneous abdominal fat. The increase in oxygen consumption capacity and the reduction in truncal fat may be primary predictors of the exercise-induced metabolic improvement in subjects submitted to PRP [22].

Karapolat et al. [23] conducted a study with an 8-week supervised exercise program and found that aerobic exercises improved functional capacity, lung capacities, QOL, and depression among patients who had heart failure, heart transplantation, or among those patients submitted to left ventricular assist device. They also concluded that supervised exercise should be recommended for every patient included in a heart transplant program. Although the beneficial effects of aerobic exercise controlling cardiovascular risk factors are known, the population's access to this type of activity is still restricted.

Korenfeld et al. [24] conducted a study on the current status of cardiac rehabilitation services in Latin America and the Caribbean. The authors assessed 98 centers in 13 countries that perform heart surgeries. They found that only 56% had cardiac rehabilitation services and among them, 70% offered treatment at all stages of rehabilitation (phases I, II and III). The study also showed that the lack of cardiac rehabilitation services was attributed to the shortage of skilled professionals (41%), budget restrictions (33%) and lack of physical area available (13%).

As many cardiology associations and World Health Organization (WHO) justify the postoperative cardiac rehabilitation and therefore supervised physical therapy in the three phases, the improvement in the quality of life of operated, it is necessary to verify the impact of physical therapy interventions in this regard, with or without photobiomodulation with LED coadjutant. For these reasons, it requires an instrument that addresses related to activities of daily living issues, general health and functional capacity. The Short-Form (36) questionnaire has been used to assess the impact of the quality of life of patients undergoing various surgical procedures like laparoscopic renal [25], pulmonary and thoracic surgery [26] and bariatric surgery [27]. Kiebzak et al. [28] showed that the Short-Form (36) can be used effectively in patients with coronary artery disease (CAD) undergoing CABG. In the preoperative phase, one of the most important areas is the emotional (AE), followed by physical (AF).

The recovery of patients that submit to coronary-artery bypass surgery is tied to a good post-operation rehabilitation program. Physical therapy's efficacy has been reported in the literature. Specifically, Physical therapy approach to respiratory problems, which can be

significant issues in the post-operative period, has been studied, as well as its ability to re-establish patient functionality. Some of the limitations of an effective rehabilitation program include the sternotomy inflammation pain caused by the surgical procedure and the risk of dehiscence that occurs when handling the chest. These limitations restrict the chest's expansion, as well as upper limb movements [29], and they are reflected in patients' functionalities, as existing with these difficulties on a daily basis has a negative effect on their psychological health. All of these factors must be considered when analysing the impact of the surgery and the physical therapy on the patient's quality of life.

Physical therapists have an important role in keeping the patients' airways free from obstructions and preventing respiratory complications after surgery. It is also important to preserve the cough reflex, which can sometimes be restricted by the patients because of chest pain. The pain can vary from moderate to intense between the immediate post-surgical period and the hospital discharge [30]. LED therapy ( $\lambda$  of  $640\pm 20$  nm) in tissue modulation showed to have an analgesic effect on the sternotomy of patients submitted to CABG during hospitalization period [12]. However, this benefit does not appear to be important in the QOL perception after hospital discharge and even in the first six months after surgery.

Tissue modulation also implies an increase in tissue resistance to rupture, which is important for preventing dehiscence [7,11] once the patients complain of chest instability. The effects of photobiomodulation on surgical wounds are more evident in the early stages of healing, resulting in increased collagen deposition, a greater number of fibroblasts and quickened re-epithelialization during the experimental time [9,31]. Although there was no incidence of sternal dehiscence in the group treated with LED, data from this study are not sufficient to conclude that there was a photobiomodulator positive influence in the QOL perception. However, cases of dehiscence occurring in other groups, indicates a likely negative impact on QOL.

The Short-Form (36) has been used in several studies to assess the impact on QOL of surgical procedures. Kiebzec et al. [28] showed that the SF-36 can be used effectively in patients with coronary artery disease after CABG surgery, whereas Székely et al. used the SF-12 and reporting it as a powerful instrument for risk stratification and planning for hospital discharge and rehabilitation [32]. Rumsfeld et al. suggested that some predictors of health-related quality of life after CABG may be useful for preoperative risk assessment counselling of patients with regard to anticipated health status outcomes [33]. At the pre-operation stage, we found that one of the most important impaired aspects was the emotional ER, followed by the PRF, whereas pain did not have any impact. These are likely due to the patients' functional restrictions caused by angina or coronary diseases as well as the influence of those restrictions on emotions and anxiety prior to CABG [30,24]. In the first month, all of the groups showed a discrete increase in emotional aspects and an indistinct decrease in PRF scores, results that were most likely influenced by the pain and the physical limitations post-surgery. The LED group, however, reported less pain, and this fact may have a positive impact on QOL. These QOL results are similar to those described by Rantanen et al. [34].

After six months, the patients' perception of their QOL had increased significantly in all aspects over their pre-operative responses. Before surgery, the presence of coronary disease, anxiety about the prognosis and surgery, and fear and physical limitations significantly impaired the patients' functional and emotional discernment. Rantanen et al. [34], using a different questionnaire, also found a post-surgical increase in all aspects, whereas Kiebzec et al. [28] found an increase in all aspects except the GH and ERF in their one-year follow-up. Although the number of participants in this study was not as substantial,

being a limitation of the study, the preliminary results showed that QOL score improved in all groups for all aspects. This increase was more significant among the individuals who joined a PRP ( $p \leq 0.05$ ), which leads us to believe that PRPs have an important role in the patient's perception of QOL. However, it is not clear whether the PRP impact was directly related to its therapeutic properties because the socializing aspect and the sense of being cared by a professional also seem to have a role in these results.

LED therapy ( $\lambda$  of  $640 \pm 20$  nm) showed to have an analgesic effect on the sternotomy of patients submitted to CABG and increases the rate of incision healing, preventing dehiscence but this effects showed no influence in QOL after hospital discharge. Although the number of participants in this study was limited, patients' QOL improved six months after surgery, particularly among those who adhered to a physical reconditioning program. The limits of this study were the difficult assessing distant patients and the control about the techniques and protocols used by their physical therapists performing the physical reconditioning program.

## **5. CONCLUSION**

The quality of life of the patients receiving LED therapy increased in the first six months after surgery, while those patients who also adhered to a physical reconditioning program supervised by a physical therapist had even better results.

## **CONSENT**

All authors declare that 'written informed consent was obtained from the patient for publication of the results of this clinical trial.

## **ETHICAL APPROVAL**

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. The research was registered at the Brazilian Clinical Trial Registry and the International Clinical Trials Registry Platform of the World Health Organization under RBR-38wgx6 and Universal Trial Number U1111-1128-9666, respectively. The register can be certified at <http://www.ensaiosclinicos.gov.br/rg/RBR-38wgx6>. All participants. All of the subjects signed a written declaration of informed consent for LED therapy and follow-up, and their rights were protected.

## **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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