Photobiostimulation in patients with shoulder impact syndrome. Randomized clinical trial

Fotobioestimulação em pacientes com síndrome do impacto do ombro. Ensaio clínico randomizado

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ABSTRACT

BACKGROUND AND OBJECTIVES: To evaluate the effects of cluster therapy (Laser+LED) on shoulder impact syndrome, aiming at modulating pain and functionality.
METHODS: Clinical, randomized, non double-blind study. Consisting of 28 individuals of both sexes, aged between 18 and 50 years, who were separated into: control group (CG n=13) and treatment group (TG n=15). The volunteers answered the Shoulder Pain and Disability Index (SPADI) questionnaire and goniometric evaluation of three active movements: flexion, abduction, and external rotation. The treatment group was submitted to Fluence Cluster – HTM, with energy of 12.8J, for 1 min and 30 seconds, 3 times a week, for 4 weeks, totaling 12 therapies, in the insertion of the tendon of the supraspinatus muscle and the passage of the long portion of the biceps brachii. The control group received orientation regarding daily activities.
RESULTS: In both groups there was a reduction in pain, but the effect size observed was greater for the treatment group In the total SPADI evaluation, treatment presented a significant reduction in values, again with a greater effect size. In active movements, both flexion and external rotation, again the group that used the cluster had advantages, both inferential and in effect sizes.
CONCLUSION: The cluster significantly reduced pain and increased functionality in patients with shoulder impingement syndrome.
Keywords: Low-level light therapy, Physical therapy specialty, Tendinopathy.

RESUMO

JUSTIFICATIVA E OBJETIVOS: Avaliar os efeitos da terapia com cluster Laser+LED na síndrome do impacto do ombro, visando modulação da dor e funcionalidade.
MÉTODOS: Estudo clínico, randomizado, não duplo-cego, que incluiu 28 indivíduos de ambos os sexos, com idade entre 18 e 50 anos, separados em grupo controle (GC n=13) e tratamento (GT n=15). Após responderem o questionário *Shoulder Pain and Disability Index* (SPADI) foi realizada avaliação goniométrica de três movimentos ativos: flexão, abdução e rotação externa. O grupo tratamento foi submetido ao *Fluence Cluster* - HTM com energia de 12,8J, durante 1 min e 30 segundos, 3 vezes por semana, durante 4 semanas, totalizando 12 terapias, na de inserção do tendão do músculo supraespinhal e passagem da porção longa do bíceps braquial. O grupo controle recebeu orientações quanto às atividades diárias.
RESULTADOS: Em ambos os grupos houve redução do quadro álgico, porém o efeito observado foi maior para o grupo tratamento. Na avaliação total do SPADI o grupo tratamento apresentou redução significativa dos valores com maior tamanho de efeito. Nos movimentos ativos, tanto flexão quanto rotação externa, o grupo tratamento apresentou vantagens, tanto de forma inferencial quanto nos tamanhos de efeito.
CONCLUSÃO: A fotobioestimulação reduziu de modo significativo a dor e aumentou a funcionalidade dos pacientes com síndrome do impacto do ombro.
Descritores: Fisioterapia, Tendinopatia, Terapia com luz de baixa intensidade.

INTRODUCTION

Shoulder impingement syndrome (SIS) is an inflammatory and degenerative disease. The most common symptom is shoulder pain due to compression and mechanical abrasion of the subacromial structures against the anteroinferior surface of the acromion and the coracoacromial ligament during arm elevation[1], especially in a range between 60 and 120 degrees[2]. Besides this painful arc, complaints usually occur when the patient remains in lateral decubitus, compressing the affected shoulder[3]. The syndrome can be defined as painful, of microtraumatic and degenerative nature and accompanied or not by loss of muscle strength[4]. SIS represents 44 to 65% of all cases of shoulder pain conditions[2]. About 33% of SIS patients present scapular dyskinesia[5], of multifactorial etiology related to functional, degenerative, and mecha-

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nical causes. Treatment can be conservative with non-hormonal anti-inflammatory drugs, infiltrations and physical therapy[3,6].
Subacromial decompression has been the therapy of choice for cases with worse development, but there is evidence that this technique is not more advantageous than conservative treatment[7], with analgesic and anti-inflammatory techniques to decrease shoulder dysfunction, improving neuromuscular control of the rotator cuff and scapular muscles, with the objective of stabilizing or adequately position the scapula during dynamic shoulder movement[2,8].
Photobiomodulation (PBM) is the use of red or infrared spectrum radiation that, by reaching specific receptors, promotes the release of chemical mediators and modifies enzyme action, favoring tissue regeneration and pain reduction[9,10]. Effects on the increase of performance in athletes, influencing muscle mass, reducing the inflammatory process and oxidative stress in muscle biopsies have been observed[10]. PBM can act in the several dysfunctions caused by the cumulative effects of the impact of the SIS development[11,12]. Although It's still commonly used in clinical practice, low-power laser therapy is not indicated in this dysfunction[8], and it's important to evaluate the effects of cluster laser+LED therapy in SIS, aiming at pain modulation, as well as general and specific functionality of active movement.

METHODS

Experimental, randomized, single evaluators-blinded study, following the CONSORT criteria, carried out at the Physical Rehabilitation Center (PRC) of the *Universidade Estadual do Oeste*, Cascavel Campus (UNIOESTE). The sample consisted of 30 volunteers of both genders, aged between 18 and 50 years old, divided into control group (CG, n=15) and treatment group (TG, n=15).
The inclusion criteria were diagnosis of impingement syndrome, unilateral or bilateral shoulder pain, and positive results in at least three tests for SIS. The exclusion criteria were having a history of cervical spine and upper limb surgery, shoulder pain of neurological or rheumatic origin, and not undergoing all the PBM sessions.
The individuals were familiarized with the procedures that would be performed, which could be destined for PBM group or orientation, signed the Free and Informed Consent Term (FICT), and answered the Shoulder Pain and Disability Index (SPADI). Next, the following tests specific for impingement syndrome were performed: Neer, Hawkins-Kennedy, Jobe, Arc Pain, Speed Test, and Gerber[13].
The SPADI, used for evaluation of shoulder associated pain and disability[14,15], consists of 13 questions, distributed in two domains: pain (five items) and function (eight items), and each item was scored on a numerical scale from zero to 10 points. The final score, as well as the score obtained separately by domain, was converted into percentages for values ranging from zero to 100, and the higher the score, the worse the condition of the dysfunction[16].
Next, they were evaluated through goniometry for the three active movements: flexion, abduction and external rotation (EV1). Only the SPADI and goniometry evaluators were blinded with respect to the groups. For randomization, the web page https://www.graphpad.com/quickcalcs/randomize1/ was used.
The TG was submitted to Fluence LED (617nm±10%, 1500mW) and Laser (830nm, 150mW, beam area 12.57mm) - HTM® (Amparo - São Paulo), with combined energy of 12.8J per area, during 1 minute and 30 seconds. The radiation was applied to the insertion region of the supraspinatus tendon and the long portion of the biceps brachii three times a week for four weeks. The CG received orientation regarding the performance of activities of daily living (ADL) and a folder about the prevention of repetitive movements of the shoulder joint. At the end of the intervention, the patients from both groups were reevaluated after 24 hours (EV2) and at 30 days' follow-up (EV3).
Study approved by the Research Ethics Committee (CEP) of UNIOESTE under number 2.958.408 in 2018.

Statistical analysis

The total sample size was calculated in 30 individuals through the G*Power 3.1.9.7 software, with an effect size of 0.53, α=0.05, and a power of 0.955. For inferential analysis, the SPSS 20.0 program was used, with analyses performed by Generalized Mixed Models, and LSD post-test. A significance level of 5% was determined in all cases. Effect size was also assessed by Cohen's d based on the first assessment for each group and classified as: <0.2: very low; 0.2-0.5: small; 0.5-0.8: moderate; >0.8: large.

RESULTS

Eighteen individuals were included, 10 men and 18 women with a mean age of 26.8±10.4 years, height 1.68±0.08m, body mass 69.39±15.04kg and body mass index 24.25±3.95 (Figure 1). The algic scenario evaluated by the SPADI questionnaire showed interaction (p=0.016). The behavior was similar in both groups, with higher values in the first evaluation and reduction in EV2 and EV3 (Table 1). However, the analysis of effect sizes, which indicates the qualitative effect of the adopted therapy, showed small effect sizes for CG (EV1-EV2 and EV1-EV3) and moderate (EV1-EV2) and large effect sizes (EV1-EV3) for the TG (Figure 2 - A and B).

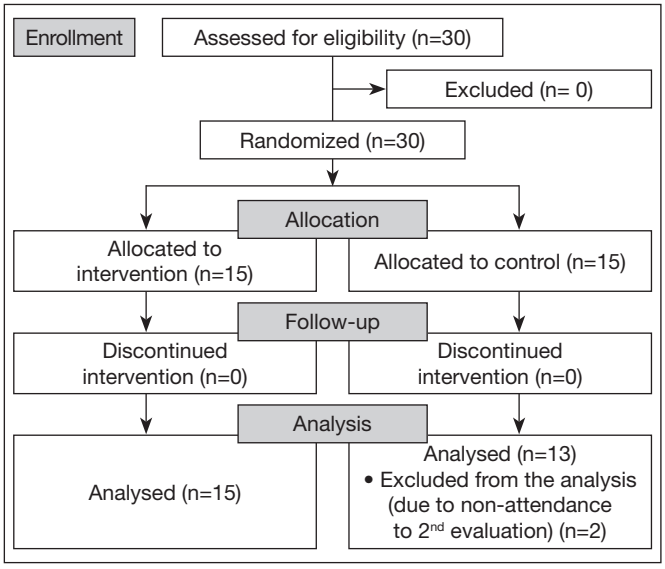

Figure 1. CONSORT 2010 flow diagram

Table 1. Condition of shoulder dysfunction in both groups

Groups	Evaluation	Pain	Disability*	Total
CG	EV1	55.1±19.6 Aa	37.9 ±24.3	44.6±21.5 Aa
	EV2	43.5±28.7 Ab	23.6±25.2	31.2±25.6 Aa
	EV3	43.5±28.7 Ab	23.6±25.2	31.2±25.6 Aa
TG	EV1	69.5±26.0 Aa	42.0±21.4	52.5±22.4 Aa
	EV2	47.9±30.0 Ab	24.6±20.0	33.7±22.8 Ab
	EV3	43.6±34.3 Ab	21.8±23.7	30.3±26.5 Ab

* Significant difference between EV1-EV2 and EV1-EV3 evaluations.
Capital letters show similarities between groups according to the time of evaluation. Different lowercase letters show differences between evaluations within the same group.

There were no differences between groups for disability (p=0.649) neither interaction of factors (p=0.522), only differences between assessments (p<0.001) (Table 1). Effect sizes were moderate for CG (EV1 with EV2 and EV3) and large for TG (EV1 with EV2 and EV3) (Figure 2 - C and D).

There was interaction (p=0.022) in the total evaluation of SPADI. There were no differences between the groups, but the TG presented higher values in EV1 compared to EV2 and EV3 (Table 1). For CG the effect sizes were very low (EV1 with EV2 and EV3) and for TG small between EV1-EV2 and moderate between EV1-EV3 (Figure 2 - E and F).

There was interaction of the ranges of motion (ROM) for flexion (p<0.001) and external rotation (p=0.016). In the first evaluation the groups were different (p=0.011) but became similar in the following. Within the groups, the CG showed similarity in the evaluations, while the TG showed a significant increase in ROM. There was also interaction for abduction (p=0.012), with CG being higher than TG in EV1 and EV2, becoming similar in EV3. In the comparison within groups, CG was always similar, whereas TG showed

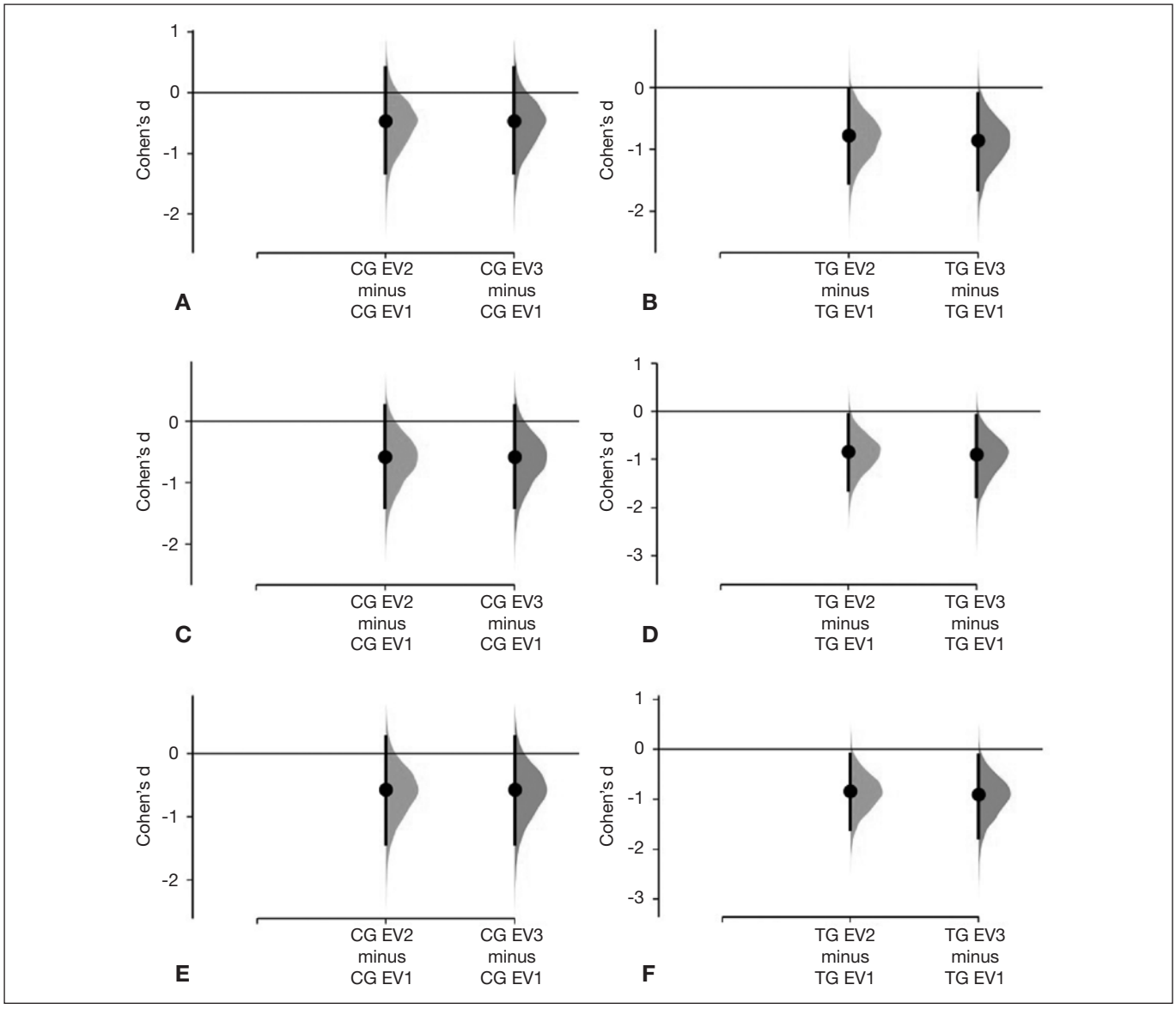

Figure 2. Size of effects obtained in the Shoulder Pain and Disability Index for pain (A - control; B - treatment), function (C - control; D - treatment), and total (E - control; F - treatment). CG = control group; TG = treatment group; EV = evaluation.

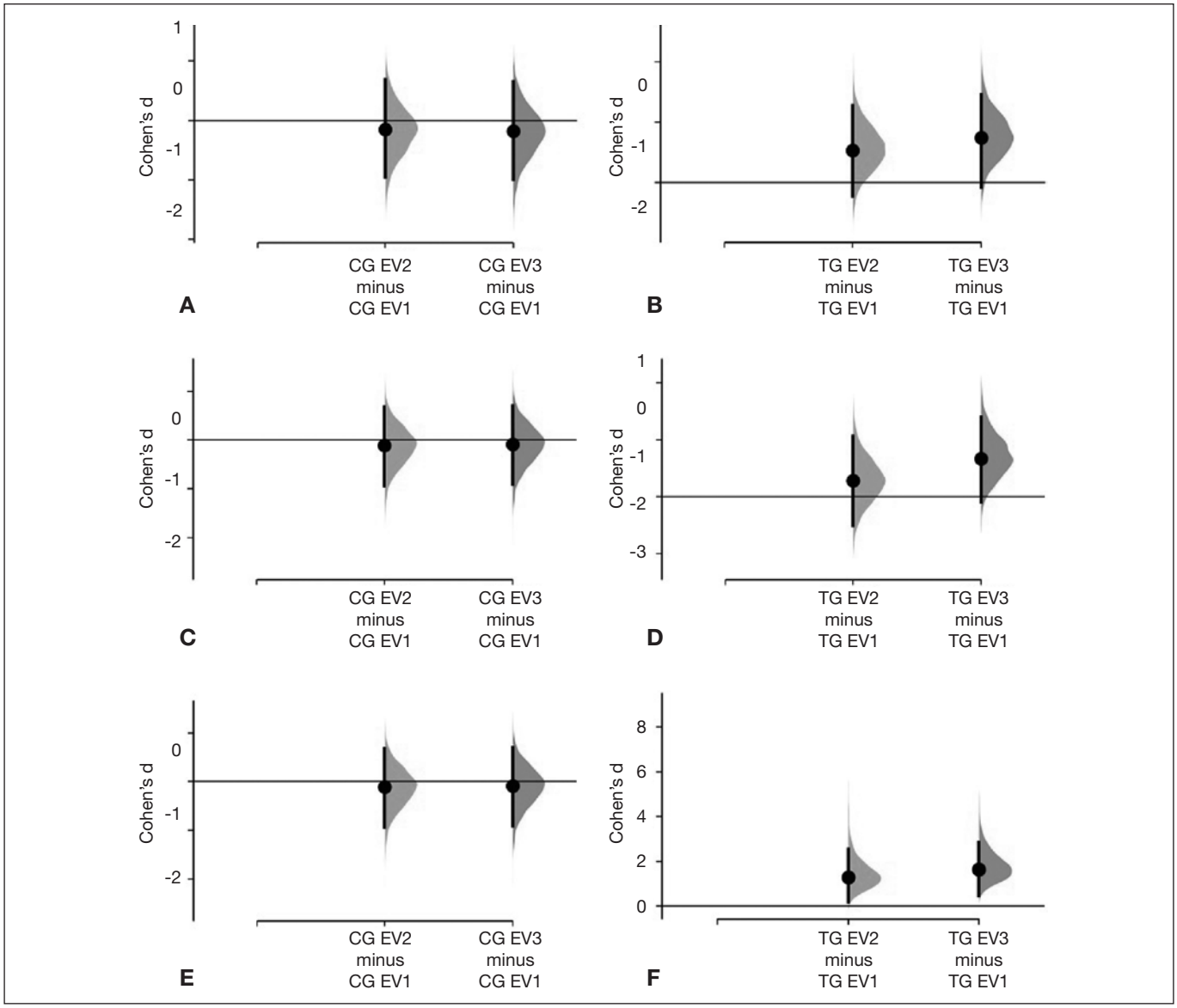

Figure 3. Presentation of effect sizes observed in range of motion specific to flexion (A - control; B - treatment), abduction (C - control; D - treatment), and external rotation (E - control; F - treatment). CG = control group; TG = treatment group; EV = evaluation.

an increase in EV2 and EV3 (Table 2). Effect sizes were very low for CG, and for TG they ranged from small to large (Figure 3).

Table 2. Data in movement degree for both groups

		FL	ABD	ROT
CG	EV1	154.8±20.9 Aa	157.9±22.3 Aa	83.5±13.0 Aa
	EV2	152.0±18.6 Aa	155.0±17.3 Aa	85.3±13.0 Aa
	EV3	151.5±17.9 Aa	156.0±16.5 Aa	85.3±11.7 Aa
TG	EV1	135.2±23.9 Ba	127.9±24.1 Ba	65.7±17.3 Ba
	EV2	144.8±24.8 Ab	138.2±28.1 Bb	80.4±15.3 Ab
	EV3	148.6±14.8 Ab	140.9±19.5 Ab	80.6±12.3 Ab

CG = control group; TG = treatment group; FL = flexion movements; ABD = abduction; ROT = external rotation.

Different capital letters represent differences between groups (for the same evaluation). Different lowercase letters represent differences within groups.

DISCUSSION

The present study showed that the isolated effect of the associated laser and LED cluster reduced pain, improved function, and ROM in individuals with SIS.

The specific SPADI questionnaire for pain and disability of the shoulder joint evaluation is recommended because it has all the assessed psychometric properties, with a numerical scale response format and short questions that facilitate its completion. The Brazilian version is validated and reliable, low cost, and feasible for research[16]. The other variable analyzed was the ROM, through goniometry, which, despite being very simple, is reliable and useful to assess small movement differences[17,18].

Laser treatments can be done with high-power equipment[12] with the 1064nm, 7W laser, in two energy densities (20 and 100J/

cm^2), obtaining pain and function improvement in two weeks of treatment. A study[19] compared the short-term effect of ultrasound therapy with a high-intensity laser with an average power of 6W during 10 treatment sessions for two consecutive weeks, and presented a significant improvement in pain, joint movement, functionality, and muscle strength in patients who underwent laser therapy compared to those who underwent ultrasound therapy. The current study confirms the result of the laser, which provided significant improvement in pain, joint movement, and functionality, despite the much lower power used.

Also comparing ultrasound with laser (850nm), but with low power (100mW), a study[20] with two weeks of treatment in individuals with SIS and follow-up between 1 and 3 months showed a reduction in pain and functional improvement, suggesting that laser can be a good alternative to ultrasound when the latter is contraindicated for treatment. Nevertheless, another study[21] did not show advantages of one form of therapy over the other in cases of SIS. Some studies that associated low power infrared laser with exercise protocols, both in clinics and at home, showed both positive[22,23] and negative[24-26] results. As an isolated treatment, the laser was as effective as corticoid injections in the shoulder[11], but inferior to treatment with shock waves[27].

Laser has analgesic and anti-inflammatory properties, helping to reduce edema by reducing the synthesis of prostaglandins and inhibiting prostacyclins, and may increase nerve stimulation and the regulation of microcirculation, explaining the sensory changes in the central nervous system[24.] Because its biostimulating activity acts on a cellular level, when it interacts with the tissue it's absorbed by the mitochondria, interacting with cytochrome C oxidase, which plays a central role in cell bioenergetics, generating a greater production of ATP, favoring tissue repair[28].

LED has also been useful in reducing inflammatory processes and pain, with significant reduction of inflammatory mediators such as prostaglandins, prostacyclins, bradykinin, substance P, histamine, interleukin-1β (IL1β) and tumor necrosis factor (TNF-α), reducing the activation of nociceptors. Furthermore, LED provides increased activity of macrophages, neutrophils, production of interleukin-10 (IL10) and increased cellular metabolism. This is due to the increase in mitotic activity, which acts in the repair process and in the improvement of the metabolic defense system related to the cellular antioxidant action in catalase and the activity of superoxide dismutase[29-31].

In the present study, orientations were given to the CG about the best way to perform the ADL and an educational folder was made available with explanations about the disease and prevention in performing repetitive movements, with significant improvement in the pain domain evaluated by the SPADI questionnaire. Technologies for health education can range from media to games, to printed content, such as serial albums and booklets with recommendations for planning, delivery, and evaluation of health care based on benefits and partnerships between health professionals, patients, and families[32,33].

Limitations of this study are the absence of image and muscle strength assessments, as well as the lack of a placebo group or total control, since health education measures may have interfered with the natural development of the dysfunction in the CG members[34].

CONCLUSION

The Laser+LED cluster provided reduction in pain and increase in functionality in patients with SIS.

AUTHORS' CONTRIBUTIONS

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Data Collection, Conceptualization, Research, Methodology, Writing - Preparation of the original, Visualization

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Statistical Analysis, Funding Acquisition, Data Collection, Conceptualization, Resource Management, Project Management, Research, Methodology, Writing - Review and Editing, Supervision

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