Original Research Article

Evaluation of vascular photobiomodulation in children and adolescents with sleep bruxism: A randomized controlled clinical trial

ABSTRACT

Objective: To evaluate the effect of the vascular photobiomodulation, also called as intravascular laser irradiation of blood (ILIB) combined with myofunctional exercises for the treatment of sleep bruxism in children and adolescents through a randomized controlled clinical trial. **Materials and methods:** Forty-six individuals with a diagnosis of bruxism between three and seventeen years of age were included. The participants were evaluated before and after treatment with the aid of questionnaires addressing sleep bruxism and sleep quality as well as the measure of nocturnal oxygen saturation. The participants were divided into two groups: G1 (ILIB) and G2 (control). G1 received active ILIB combined with an orofacial myofunctional exercise protocol. G2 received sham ILIB and the exercise protocol. Once-a-week during four weeks, 10-minute active/sham laser sessions were held for each participant. After each active/sham laser session, myofunctional therapy was performed and the participants were instructed to continue the exercises twice a day for five minutes each time. **Results:**improvements in swallowing, breathing and chewing were found for all patients in both groups, with no significant difference between groups. The reduction in bruxism was significantly greater ($p < 0.05$) in G1 (ILIB) compared to G2 (control). A weak to nil linear relationship between bruxism and oxygen saturation was found in both groups. **Conclusion:** ILIB favored a reduction in bruxism but was not decisive in improving orofacial functions, such as breathing, swallowing and chewing. However, orofacial myofunctional therapy was effective at reducing conditions related to this sleep disorder.

Keywords: Bruxism; Intravascular Irradiation of Blood; Myofunctional Therapy; Oximetry;Photobiomodulation.

1. INTRODUCTION

Sleep bruxism (SB) was considered a disorder related to tooth wear and other occlusal characteristics and part of the micro-arousal phenomenon (waking for short periods during sleep). Recently, however, neurological and central associations have been investigated and bruxism is no longer considered an activity that emerges from occlusal interferences [1]. SB is currently considered masticatory muscle activity during sleep with rhythmic (fascia) or non-rhythmic (tonic) characteristics [2], altering the conception of SB as a parafunction (activity parallel to masticatory function) and understanding it to be a behavior with possible negative consequences [3].

The prevalence of SB among children and adolescents ranges from 3% to 49% [4].This condition in children and adolescents can have negative consequences if not identified and treated in a timely manner and the most common symptoms are pain in the temporomandibular joint, masticatory muscles and neck muscles, headache, noise due to the grinding of the teeth, earache, tooth hypersensitivity, a lack of rest and, consequently, the sensation of fatigue [5,6,7]. The etiology of SB is multifactorial, as the condition may be associated with an altered breathing pattern and poor sleep quality [8], genetic causes, such as possible polymorphisms, anxiety, some personality traits and stress-related endocrine changes [9, 10].

The diagnosis of SB is established based on grinding or clenching the teeth during sleep, abnormal tooth wear, sounds related to bruxism and discomfort in jaw muscles [9]. According to the 2018 consensus, possible SB is based only on the report of the patient or parents/guardians. The probable BS is based on the presence of any of the clinical signs, and there may or may not be a positive report from the patient or guardians [3]. However, polysomnography (PSG) is the 'gold standard' for the diagnosis of definite SB, as this method enables the simultaneous monitoring of electroencephalographic, electrocardiographic and respiratory signs during sleep [11]. However, due to the high cost of PSG, self-administered questionnaires (completed by parents or guardians for pediatric patients) are generally used, with the diagnosis established based on the criteria recommended by the American Sleep Medicine Association [12,13].

Therapeutic options for SB are generally palliative, involving the treatment of symptoms without addressing the genesis of the behavior. Evidence on the effectiveness of medications for children and adolescents is scarce [14].

Physiotherapy treatments can be considered a non-invasive alternative for the treatment of bruxism. In many cases, physiotherapy can prevent the need for invasive procedures and even the use of medication. Treatment ranges from educational guidelines focused on care and practices to inhibit parafunctional habits to exercises that help relax the masticatory muscles [15].

Quintero et al. carried out a study evaluating physical therapy intervention for bruxist children. The children were randomly distributed in an experimental and a control group. A physiotherapeutic intervention was applied in the experimental group once a week for 10 weeks. After the intervention, 77% and 15% of parents reported a reduction of SB in the experimental and control group, respectively. The authors suggested that the physiotherapeutic intervention showed to be efficient to improve the head posture in the studied children and what more work is required to evaluate the long-standing results of the physiotherapeutic intervention on bruxism and the head posture in children [16].

There is insufficient evidence to recommend a protocol for the treatment of SB for children and adolescents. Thus, new studies with standardized diagnostic methods, representative samples, and presence of control groups must be carried out to better understand the effectiveness of SB treatment for children and adolescents. The choice for conservative treatments based on diagnosis and management of SB risk factors, as well as sleep hygiene, seems to be the first-choice therapy. The indications, contraindications, and side effects of the administration of drugs, medicinal extracts, and use of interocclusal devices must be individually evaluated [17].

Orofacial myofunctional therapy (MFT) and the intravascular laser irradiation of blood (ILIB) seem to be promising for the treatment of SB. Orofacial (MFT) consists of a set of techniques and procedures aimed at promoting changes in muscle patterns through isotonic and isometric exercises for orofacial and oropharyngeal muscles to enable improvements in the functions of breathing, chewing, swallowing and speech [18]. Thus, Orofacial MFT offers the possibility of modulating postural habits and some behavioral aspects that can directly affect SB.

Intravascular Irradiation of Blood (ILIB), a systemic modality of PBM, can be used as a complementary therapy to other therapies. The ILIB is considered a very promising method of systemic photobiomodulation. This method is painless and inexpensive that is capable of either stimulating or inhibiting cellular processes [19]. Light is used to stimulate the immune system and promote the tissue repair process. According to the literature, ILIB produces therapeutic effects, such as neurotransmitter regulation and synchronization [20], emitting energy that activates neuro-humoral regulation and synchronization and cellular modulation, with antioxidant, metabolic, immunological, antispasmodic, sedative, healing, analgesic and anti-inflammatory properties. Additional effects include an increase in blood circulation, the stimulation of the limbic system and hypothalamus, a hormonal effect that contributes to regulating sleep and mood and the normalization of endorphin and serotonin levels, generating wellbeing and improving quality of life [21, 22].

Therefore, the aim of the present study was to investigate the effectiveness of ILIB combined with orofacial myofunctional therapy for the treatment of sleep bruxism in a randomized controlled clinical trial involving children and adolescents between three and seventeen years of age.

2. MATERIAL AND METHODS

2.1 Ethical aspects

A randomized, controlled, parallel-group, single-blind, clinical trial was conducted involving children and adolescents with a diagnosis of sleep bruxism. The project received approval from the Human Research Ethics Committee of Universidad Católica del Uruguay (process number: 220211) and was registered with the Clinical Trials (https://clinicaltrials.gov/) under number NCT05301452. The guardians of the children agreed to participate by signing a statement of informed consent; two copies of which were signed: one for the guardian and one for the researchers. They were also informed that they could withdraw from the study at any time for any reason if they so wished. The researchers also had the ability to remove participants from the study if deemed necessary.

2.2 Study Population

Forty-six children and adolescents between three and seventeen years of age were recruited from the Dentistry Clinic of Universidad Católica del Uruguay during the period of September 1st and December 20th, 2022. The participants were randomly allocated to two groups. G1 received active ILIB combined with an orofacial MFT exercise protocol and G2 received sham ILIB combined with an orofacial MFT exercise protocol.

2.2.1 Inclusion criteria:

• Children and adolescents between 3 and 17 years of age diagnosed with sleep bruxism that are in treatment for other conditions at the dentistry clinic of the Universidad Católica del Uruguay

• Male and female children and adolescents diagnosed with SB;

2.2.2 Exclusion criteria:
• Individuals with dental caries.
• Use of medications, such as anti-inflammatory agents, muscle relaxants, corticosteroids, anticonvulsants, and antidepressants;
• Presence of chronic diseases that affect the muscles or motor coordination;
• Children with cerebral palsy;
• Failure to cooperate during the examination.

2.3 Sample size

The sample was calculated to detect a significant difference between PBM and MFT with 80% power and a significance level of 5%, considering the oxygen saturation index. Based on the study by Aarab et al [23] to detect a difference in saturation index, with an effect size of 0.53, the minimum number per group should be 23 participants per group.

2.4 Randomization

To randomly distribute the individuals into the experimental groups, a random sequence generator (https://www.randomizer.org/tutorial/) was used. Opaque envelopes were labeled with individual numbers, and inside each one, a sheet containing information about the corresponding experimental group was inserted. The sequence generation and envelope preparation were carried out by a person who was not involved in the study.

2.5 Blinding
The participants did not know whether they belonged to the active ILIB or sham ILIB, as the laser application was simulated. Unblinding was not permissible.

2.6 Interventions

Allocation of the participants to the different groups was performed using a randomization model from the site www.randomizer.com. The participants were allocated to two treatment groups: G1 (active ILIB and orofacial MFT) and G2 (sham ILIB combined and orofacial MFT).

Parents/guardians answered a questionnaire addressing bruxism [24] and completed the Pittsburgh Sleep Quality (PAQ) index [25]. Nocturnal oximetry was also performed at the home of each participant. Oral functions were assessed by a specialist in orofacial movements. Breathing pattern was investigated using the Glatzel mirror. The Payne method was used for the assessment of swallowing, which investigates tongue posture at rest and during functioning (swallowing). A functional assessment of chewing was performed by the specialist in orofacial movements trained and calibrated.

The participants didn't know whether they belong to G1(active ILIB) or G2 (sham ILIB) group seeing as the laser application will be simulated. Unblinding was not permissible. ILIB was performed with red laser irradiation on the radial point with a wristband. Treatment was performed at a wavelength of 660 nm once a week for four weeks, with approximately 10 minutes per session. The G1 received active ILIB protocol and G2 received sham ILIB, with the simulation of the procedure while the laser turned off [26].

The specialist in orofacial movements performed myofunctional therapy [27,28] exercise and the participants were instructed to continue the exercises twice a day in five-minute sessions. The exercises were lingual-palatal fixation, lingual pressure against the hard palate, inflated cheeks with tongue on palate and alternated chewing in the posterior region. At the end of the fourth week after the ILIB and exercise sessions, nocturnal oximetry and the assessment of orofacial functions were performed again, along with the administration of the sleep quality and bruxism questionnaires [24,25]. Thus, each participant was submitted to two assessments – before and after the end of treatment.

2.7 Data analysis

The PSQ, bruxism questionnaire, % oxygen saturation (%O_2sat), swallowing, chewing and respiration were determined before (T0) and after (T1) treatment with active or sham intravascular laser irradiation of the blood and orofacial therapy in a sample of 46 individuals divided into two groups: G1 (active ILIB) and G2 (sham ILIB). The variables were first submitted to descriptive analysis, followed by hypothesis tests to determine changes in the variables after each treatment, comparing the effects. The linear relationship between bruxism and %O_2 sat was then investigated in each group. All graphs, calculations and hypothesis tests were performed using the R program, V 4.3.1.

3. RESULTS

Fifty-two participants were evaluated, of which 48 were randomizede 46 treated, and followed up (Figure 1).

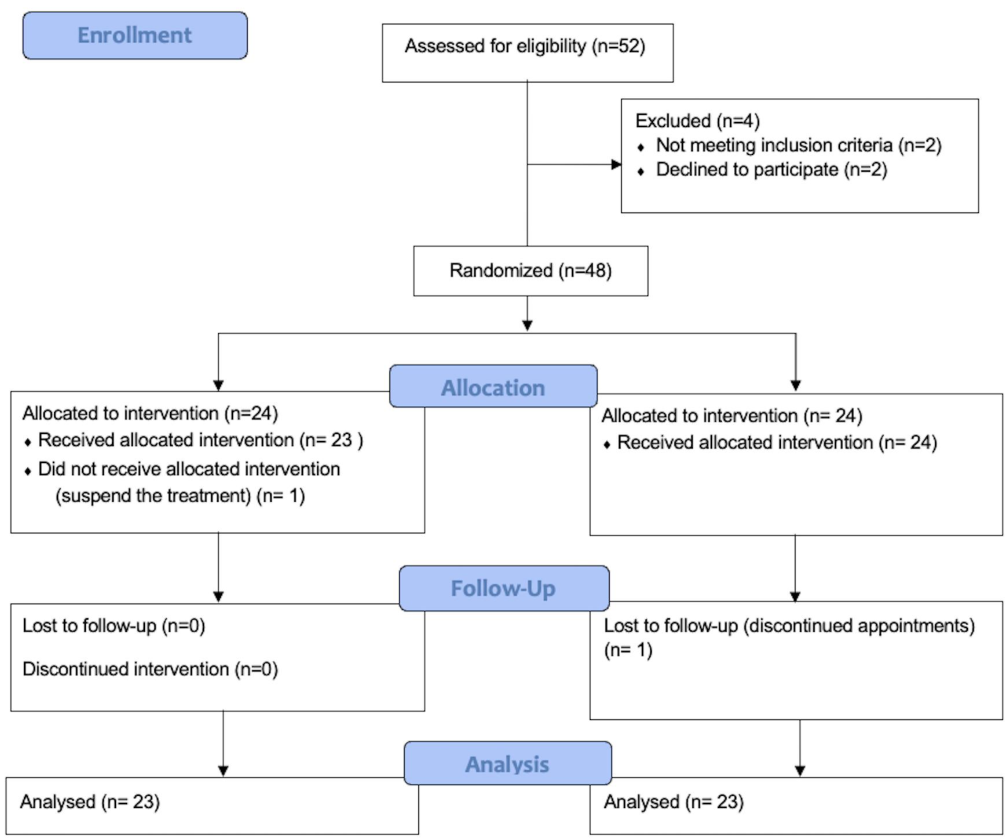

Figure 1. Flow diagram of the study according to CONSORT 2010.

3.1 Swallowing, breathing and chewing

Evaluated by a speech therapist specializing in Orofacial Motor Skills, before and after the combined treatment for four weeks. The evaluation was carried out with an estimation scale (1=altered, 0=normal) to estimate:

-The respiratory characterization from the air intake, which explains the anatomical and topographic situation of its entry into the respiratory system (respiratory mode), to the thoracoabdominal movement zone that integrates inspiration and expiration. For this evaluation, observation was made with the help of a Glatzel mirror in order to anatomically determine the state of the upper respiratory tract and its functional correlation.

- For swallowing, the Payne test was used, which evaluates the posture of the tongue both at rest and in function (swallowing).

3.2 Functional assessment by the Orofacial Motor specialist was used for chewing

After the evaluation, it was determined that these three variables showed improvement in all patients after both treatments (from value 1 to value 0). Therefore, they present no deviation, and the confidence interval has a single value, as can be seen in Tables 1, 2, and 3.

Table 1. Means and confidence intervals for chewing G1 and G2

T	$\overline{x}(Chew)G1$	$IC\ (Chew)G1$	$\overline{x}(Chew)G2$	$IC\ (Chew)G2$
0	1	1 – 1	1	1 – 1
1	0	0 – 0	0	0 – 0

Table 2. Means and confidence intervals Respiration G1 and G2

T	$\overline{x}(Resp.)G1$	$IC(Resp.)G1$	$\overline{x}(Resp.)G2$	$IC(Resp.)G2$
0	1	1 – 1	1	1 – 1
1	0	0 – 0	0	0 – 0

Table 3. Means and confidence intervals Swallowing G1 and G2

T	$\bar{x}(Deg.)G1$	$IC\ (Deg.)G1$	$\bar{x}(Deg.)G2$	$IC\ (Deg.)G2$
0	1	1 – 1	1	1 – 1
1	0	0 – 0	0	0 – 0

However, when comparing the results of G1 and G2 it is observed that there were no differences, since both treatments are equally effective having improved in all patients (p-value 0), as can be seen in the Table 4.

Table 4. P-values of the swallowing, breathing and chewing variables between G1 and G2.

Variable	p-value G1	p-valueG2
Chewing	0	0
Breathing	0	0
Swallowing	0	0

3.3 Pittsburgh Sleep Quality- PSQ

The Pittsburgh Sleep Quality questionnaire was administered to the parents/guardians before and after treatment. A significant improvement was found in G1 following treatment, the null hypothesis was rejected for PSQ, as a significant reduction in the score was found following the application of active ILIB. In the intergroup analysis, the improvement in the PSQ score was greater in G1 compared to G2, as shown in Figure 2.

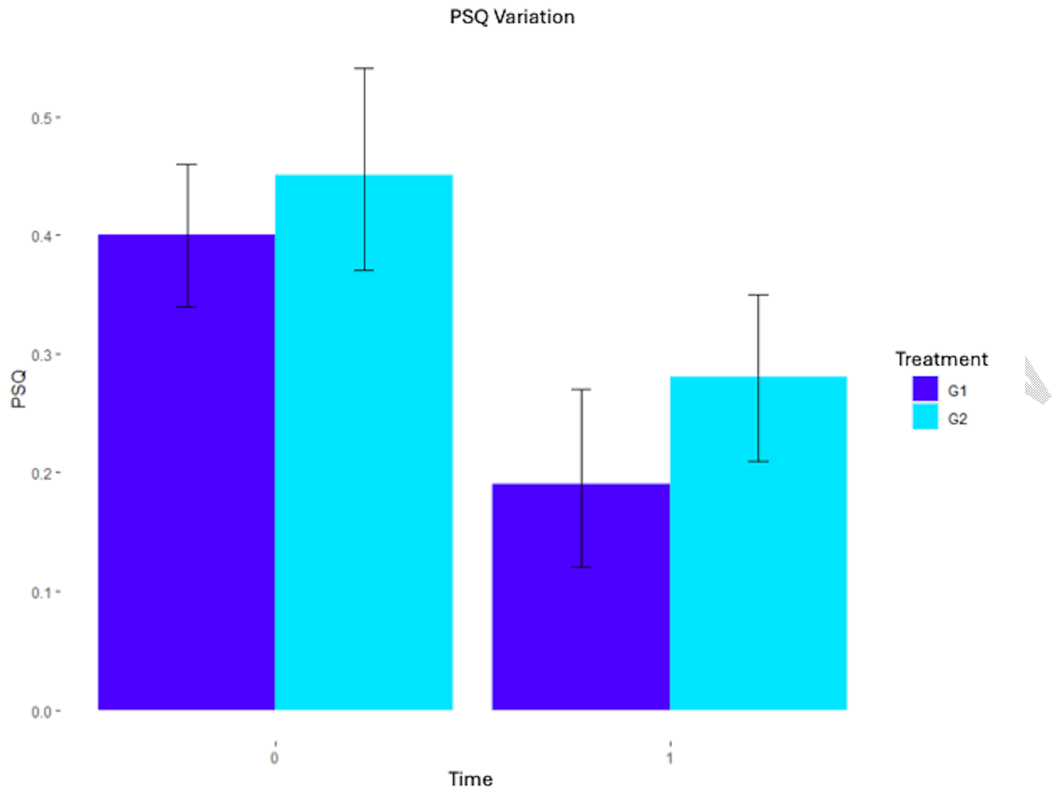

Figure 2. Change in PSQ score in G1 and G2.

3.4 Bruxism

The parents/guardians answered the questionnaire addressing bruxism before and after treatment. Table 5 displays the bruxism scores before and after treatment in G1.

Variable	T0	T1	p-value
	$\bar{x}$	$\bar{x}$	
Bruxism	1.6	0.7	0.001

Table 5. Mean bruxism score before and after treatment in G1

Based on the data displayed in Table 5, the null hypothesis was rejected for bruxism, as a significant reduction in the score was found following the application of active ILIB. In the intergroup analysis, the improvement in the bruxism score was significantly greater in G1 compared to G2, as shown in Figure 3.

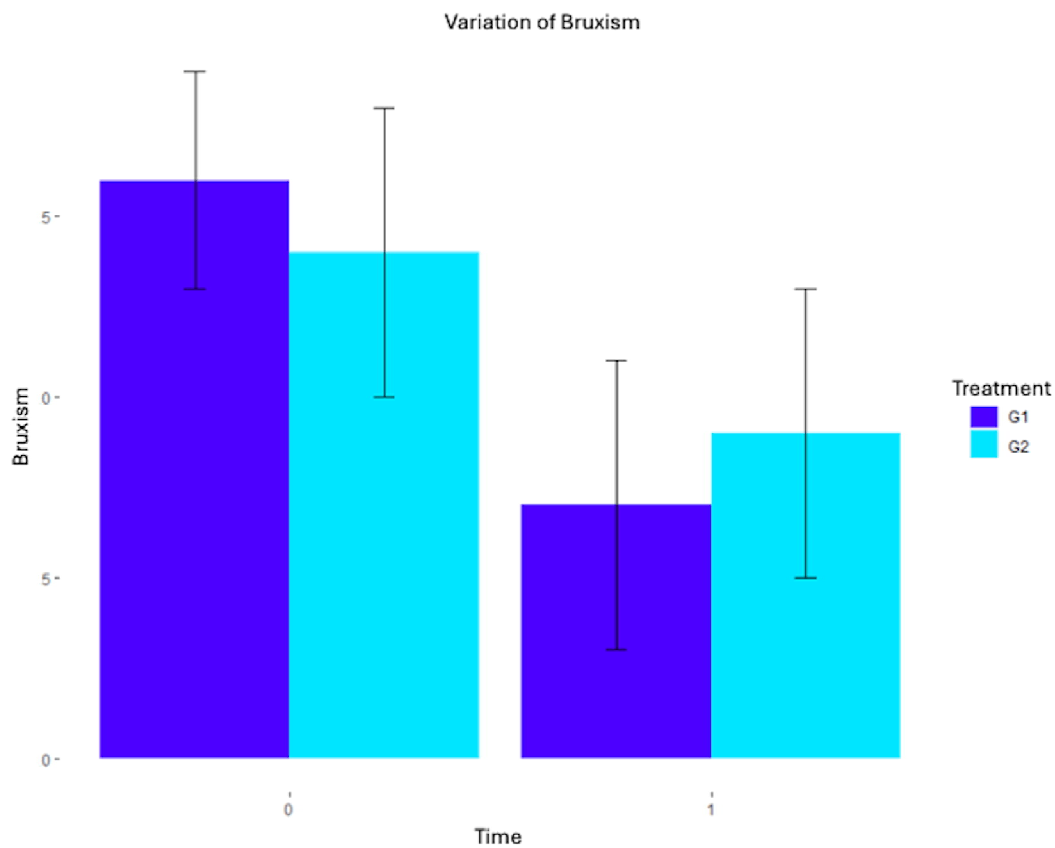

Figure 3. Variation in bruxism score Treatment Time in G1 and G2.

3.5 Oxygen Saturation

No significant difference in $\%O_2$sat was found after treatment in G1 ($p = 0.105$) (Table 6). In contrast, a significant improvement was found in G2 ($p < 0.05$), with oxygen saturation going from 96.2% before treatment to 96.9% after treatment.

Table 6. Mean oxygen saturation before and after treatment in G1

Variable	T0	T1	p-value
	$\bar{x}$	$\bar{x}$	
% O_2 saturation	96.6	96.9	0.105

3.6 Regression of bruxism and oxygen saturation

The linear relationship between bruxism and $\%O_2$ sat was weak or nil in both groups, as demonstrated by the low R^2 values and p-values higher than 0.05. A better linear relationship was found in G1 compared to G2, although the data indicate a weak relationship in both cases (Table 7).

Table 7. Linear regression parameters of bruxism vs. $\%O_2$ sat in G1 and G2

Treatment	R^2	p-value
G1	0.0815	0.1977
G2	< 0.0001	0.9741

4. DISCUSSION

Both treatments were equally effective at improving the variables related to orofacial functions (breathing, chewing and swallowing), with no significant difference found between G1 and G2. This demonstrates that Orofacial MFT was effective in the treatment of SB, whereas ILIB was not decisive in the improvement in these orofacial functions in patients with SB.

The results of the present study with regards to the effects of Orofacial MFT are compatible with data reported in the literature, demonstrating that treatment with these exercises has a positive impact on orofacial functions that are affected by bruxism [21]. The aim of these myofunctional exercises is to strengthen the dilating muscles of the pharynx to reduce its collapsibility, thus improving the endurance, neuromuscular coordination, stability and tone of this muscle group [22]. Orofacial MFT can be administered by a speech therapist to correct orofacial muscle imbalance and abnormal swallowing patterns derived from bite and speech complications [21]. Thus, speech therapists constitute an important component of the multidisciplinary team, as such health care providers are responsible for structural and functional aspects of the orofacial and neck region with the aim of achieving balance in the stomatognathic system [22].

The finding that ILIB was not decisive in the improvement in orofacial functions may be related to the fact that this therapeutic modality is more effective in other systems of the body, such as the lymphatic system [23]. In contrast, significant improvements were found in sleep quality and bruxism, with improvements in the PSQ found in both groups and a greater improvement in bruxism found in G1, which indicates that ILIB favored the reduction in bruxism in the participants. A significant improvement in the percentage of O2 saturation was only found in G2 ($p < 0.05$). Therefore, although encouraging, the results are not conclusive. Future studies should combine both therapies into a single group, which may provide promising results.

Therefore, the quest for possible therapeutic options for SB continues, especially in children and adolescents, as studies indicate that psychopathological, neuropathological and neurochemical aspects may be present in SB due to the modulation of neurotransmitters [3,26,29]. Moreover, the multifactorial etiology, which further complicates the establishment of an ideal therapy for affected individuals, leads us to believe that treatment for SB should have a multidisciplinary approach, with the involvement of dentists, speech therapists and psychologists [30].

CONCLUSION

Intravascular laser irradiation of the blood favored a reduction in bruxism and PSQ scores but was not decisive in the improvement of oxygen saturation or orofacial functions, such as breathing, swallowing and chewing.

In conclusion, intravascular laser irradiation of the blood showed promise in reducing bruxism and PSQ scores. However, its impact on improving oxygen saturation and orofacial functions, including breathing, swallowing, and chewing, was not conclusive. These findings suggest that while Intravascular laser irradiation of the blood may offer significant benefits in bruxism management, additional approaches may be necessary to fully address other aspects of orofacial function. Further research is warranted to fully understand the therapeutic potential of intravascular laser irradiation and its effects on orofacial functions in patients with bruxism.

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DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AItechnologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

AUTHORS' CONTRIBUTIONS

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

CONSENT AND ETHICAL APPROVAL

Human Research Ethics Committee of Universidad Católica del Uruguay (process number: 220211) and was registered with the Clinical Trials (https://clinicaltrials.gov/) under number NCT05301452. The guardians of the children agreed to participate by signing a statement of informed consent; two copies of which were signed: one for the guardian and one for the researchers.

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