Photobiomodulation and glass ionomer sealant as complementary treatment for hypersensitivity in molar incisor hypomineralisation in children: protocol for a blinded randomised clinical trial

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ABSTRACT

Introduction Photobiomodulation has been widely used as a complementary treatment for dentin hypersensitivity, with reports of clinical success. However, the literature offers only one study, in which photobiomodulation was used for the treatment of sensitivity in molars with molar incisor hypomineralisation (MIH). The aim of the proposed study is to determine whether photobiomodulation enhances the results of treatment with glass ionomer sealant on molars with MIH that present sensitivity.

Methods and analysis The study involves 50 patients from 6 to 12 years of age that will be randomly allocated in two groups. Group 1 (control group) (n=25): toothpaste with a concentration of fluoride ≤1000 ppm two times a day, glass ionomer sealant and sham low-level laser (LLL) and group 2 (n=25): toothpaste with a concentration of fluoride ≤1000 ppm two times a day, glass ionomer sealant and active LLL. The evaluations will involve MIH record, Simplified Oral Hygiene Index (OHI), Schiff Cold Air Sensitivity Scale (SCASS) and visual analogue scale (VAS) before the procedure. Immediately after the procedure, the hypersensitivity index (SCASS/VAS) will be registered. Records of OHI and SCASS/VAS will be registered after 48 hours as well as 1 month after the procedure. The persistence of the sealant will also be registered. It is expected that by the second consultation, a decrease in sensitivity will be observed due to the treatments received in the two groups.

Ethics and dissemination This protocol has been approved by the local medical ethical committee (certification: CEUCU 220516). The findings will be published in a peer-reviewed journal.

Trial registration number NCT05370417.

INTRODUCTION

Molar incisor hypomineralisation (MIH) is a qualitative change in the enamel of a systemic origin that presents clinically as demarcated opacities on one or more permanent first molars. This condition also often—but not necessarily—affects the incisors. MIH was first described by Weerheijm et al.1 The opacities may be whitish, yellow or brown, depending on the severity. The prevalence of MIH is 14.2% but varies depending on the region studied as well as due to the lack of assessment criteria and insufficient information in different studies, which hinders comparisons between investigations.2

MIH poses a challenge to paediatric dentists due to its unique characteristics. Structurally, areas with MIH are more porous, have a greater content of proteins and carbonate as well as a lower content of calcium and phosphorus,1 which diminishes both the hardness and elasticity of the affected area. This porosity implies complications that require a greater number of dental appointments.3

Due to the lower hardness of hypomineralised
regions, post-eruptive fractures may occur, exposing the dentin and increasing the risk of caries.  

Another characteristic of molars with MIH is hypersensitivity. Although the degree is greater in more severe cases, hypersensitivity can also be found in patients with MIH when there is no visible defect. Dentin hypersensitivity is a pain response to certain thermal, chemical or tactile stimuli. This hypersensitivity may occur during the ingestion of hot or cold foods, toothbrushing or even spontaneously on teeth with different degrees of MIH. Difficulty ingesting certain foods only occurs in severe cases of MIH.  

In the systematic review by Da Cunha Goelho et al. and the study by Bekes et al., the use of toothpaste with 8% arginine was indicated as a desensitising agent for teeth with MIH. One study reported the effectiveness of fluoride varnish, which is used more in the treatment of non-MIH hypersensitivity. Biondi and colleagues and Ozgul and colleagues reported the effectiveness of another compound (casein phosphopeptide–amorphous calcium phosphate) used in toothpastes. According to the systematic review cited, however, further studies are needed before this compound can be recommended for use.  

The application of fluoride has been successfully used as a remineralising and desensitising agent for more than 50 years. This compound promotes the precipitation of calcium fluoride and fluorapatite, which block dentinal tubules, leading to a reduction in hypersensitivity. Teaching a proper brushing technique and the use of fluoridated toothpastes also lead to a reduction in hypersensitivity and the consequent restoration of the function of affected molars.  

Lygidakis and colleagues used resin sealants with different adhesion methods. Fragelli et al and Grossi et al used glass ionomer restorations and obtained excellent results with 12 months of follow-up. These glass ionomer restorations are performed on teeth with fractures and/or caries using the concepts of minimal intervention and atraumatic restorative treatment. However, no studies have evaluated the use of glass ionomer sealants as treatment for hypersensitivity.  

In 1985, Matsumoto et al proposed a treatment with laser to diminish hypersensitivity. High-power laser was used in areas with hypersensitivity not related to MIH. The technique involves the use of laser, such as Nd:YAG, Er:YAG, Er, Cr:YSGG and CO2, for the direct obliteration of open dentinal tubules, thereby reducing the movement of fluids in the tubules and treating hypersensitivity at the origin in accordance with hydrodynamic therapy proposed by Brannstrom in 1979. The use of high-power lasers obliterates the dentinal tubules by the fusion of the dentinal surface but generates high temperatures that can cause irreversible pulp damage, which is why this technique has been replaced with other methods.  

Photobiomodulation (PBM) with low-level laser (LLL), such as GaAlAs or He-Ne, administered with adequate parameters has no adverse effects. The mechanism of action is based on the induction of changes in nerve transmission to control pain. The nerve cell is stimulated and the sodium/potassium pump in its membrane increases the amplitude of the action potential, thereby blocking the transmission of the pain stimulus. Moreover, the effect of PBM through the application of LLL promotes irrigation and cell regeneration capacity and reduces inflammation.  

In 2019, Rezaazadeh et al conducted a systematic review to assess the effectiveness of laser in the treatment and prevention of dentinal hypersensitivity not specifically related to MIH. The findings suggest that treatment with laser obtained the same results as other desensitising agents in some cases, but most studies found better, faster and long lasting results. The effects of laser applied before and after restorative treatment to reduce hypersensitivity were also evaluated.  

Muñiz et al conducted the first study on the use of PBM as a complement to treatment with fluoride varnish to diminish hypersensitivity in teeth with MIH. The results revealed that treatment with laser leads to a better immediate result compared with the application of a high concentration of fluoride as well as a better long-term result. The aim of this study is to use glass ionomer sealant and LLL to reduce hypersensitivity in molars with grades 3 and 4 MIH according to the MIH Treatment Need Index described by Steffen et al and hypersensitivity on the visual analogue scale (VAS).  

The use of glass ionomer sealants for the treatment of sensitivity in molars with MIH has not been adequately studied in the literature. These sealants can also prevent caries and fractures on teeth affected by MIH. The capacity to interact with dental tissues and the favourable adherence to teeth with structural defects tested in previous studies involving the use of these materials to restore teeth with fractures or caries led us to believe that this technique would be good treatment option. Moreover, considering the successful use of laser on cervical restorations in previous studies on dentinal hypersensitivity, we believe that the administration of laser prior to the application of the glass ionomer sealant would be a good combination.  

With this study, we hope to determine the effectiveness of treatment involving glass ionomer sealant combined with LLL to take advantage of the benefits of PBM in patients with MIH and hypersensitivity, thereby improving pain and enabling the better brushing of affected teeth. We expect these treatments to constitute an option for pain relief in patients with hypersensitivity in molars with MIH.  

**METHODS**  
A randomised, controlled clinical trial was designed based on the Consolidated Standards of Reporting Trials statement.  

This protocol follows the Standard Protocol Items for Randomized Trials recommendations, as displayed in table 1.
**Description of sample**

Male and female patients will be recruited from the internal and external clinics of the School of Health Sciences of *Universidade Católica do Uruguai* as well as a private dental office. All participants will need to meet the eligibility criteria described below and have a signed statement of informed consent.

**Participants**

**Inclusion criteria**

Healthy individuals (ASA (American Society of Anaesthesiologists) I—negative medical history) will be included. Female and male patients 6–12 years of age with at least one permanent first molar with MIH (all degrees of opacities) according to the MIH Treatment Need Index, grades 3 and 4, described by Steffen *et al.*, and hypersensitivity on the VAS scale and the Schiff Cold Air Sensitivity Scale (SCASS) will be selected. As the sample unit will be the molar, a single patient may have more than one molar studied. Molars with post enamel breakdown will be included as long as there is no pulp involvement or active carious lesions.

The molars included will have an eruption of the entire occlusal face and at least one-third of the buccal face, so that the treatment can be applied.

**Exclusion criteria**

Molars with caries activity (which can confound the aetiology of hypersensitivity with pulpitis) and those who underwent any desensitising treatment in the previous 3 months (other than habitual toothpaste) will be excluded. Individuals wearing a fixed orthodontic appliance with bands or tubes located on the first molars (which could alter the surfaces), those with an adverse reaction or discomfort during the hypersensitivity test and those who do not tolerate the procedure during the study will also be excluded.

Patients with behavioural difficulties will be treated as in any paediatric dentistry procedure, trying to obtain a positive response. In case of not achieving collaboration, they will be excluded from the study.

**Patient and public involvement**

The guardians of the patients were not involved in the design of this study. After the data analysis, the guardians will be given the opportunity to participate in a result-sharing meeting if they so desire. The consent form signed by guardians of the participants explains that the storage of data for each participant and family member is within the terms of confidentiality.

**Calculation of sample size**

This is a non-inferiority trial. The sample size was calculated using the G* Power software programme (V.3.1.9.2) based on the study conducted by Muniz *et al.* Considering an effect size of 0.80 for the primary outcome (sensitivity score) and assuming a possible 10% dropout rate, a total of 50 patients (25 in each group) will be needed to ensure a 5% significance level and 90% power. The Shapiro Wilk test will be performed to determine the normality of the data, the SD and 95% CI will be calculated. If the data are parametric, the t-test for independent samples will be used for comparison between groups, and the comparison between times in the same group will be done with
the t-test for dependent samples. If the data are non-parametric, the Mann-Whitney test will be used intergroups and the intragroups comparison between times will be done with the Wilcoxon test.

Randomisation
The participants will be randomly allocated to two groups using a randomisation site (randomization.com):

Group 1 (control group) (n=25): toothpaste with a concentration of fluoride, glass ionomer sealant and sham LLL.

Group 2 (n=25): toothpaste with a concentration of fluoride, glass ionomer sealant and active LLL.

Blinding
In the case of patients to group 1, the application of low-intensity laser will be simulated in the group 1 to maintain the study blind.

Interventions
The study will be carried out by a research team that will include one examiner, who will perform the application (or simulation of the application) of the PBM and perform the sealants on the corresponding molars. The same examiner will carry out the pre and postevaluations.

For toothbrushing, instructions will be given to patients, and they will brush as they usually do at home two times a day with a 1000 ppm F toothpaste. All patients will receive a toothbrush and toothpaste for standardisation. The objective of this intervention is to compare whether the brushing performed by the patient improves with desensitisation. If parents usually review brushing at home, this behaviour will not change.

For sealants, Ketac Molar EasyMix Glass Ionomer from 3M will be used.

Protocol of application:
Preparation: clean the surface to be sealed with a brush and prophylactic paste.
Conditioning: the liquid must be applied.
Ketac Molar EasyMix to the prepared surfaces and the substance(s) should be allowed to react for 10s. After this, rinse with plenty of water and air dry in 2–3 short intervals with water and oil-free air or dry with cotton swabs.
Mix the powder and liquid according to the manufacturer’s instructions to achieve a homogeneous product. The material is applied in pits and fissures.
A small amount of Vaseline is placed on your finger and use it to press the cement of glass ionomer in fissures and retentions—finger printing technique.
The occlusion must be controlled and the patient cannot receive pressure for 1 hour.
For laser application, the following dosimetric parameters will be used: low-level laser diode infrared (DMC, São Carlos, Brazil) wavelength 808 nm with a power of 100 mW. It will be applied in three perpendicular points and in contact with the surface, in the vestibular mesial and distal cervical thirds, and in the centre of the opacity. It will be applied for 10 s per point with an energy of 1 J.

The estimated time of the consultations will be half an hour.

**Group 1 (control group)**
Toothbrushing with a ≥1000 ppm concentration of F toothpaste two times per day, glass ionomer sealant and sham LLL (Sham LLL).

In the first consultation, the preoperative records, brushing instruction, sealants, postsealant records and the application of Sham LLL...

**Group 2**
Toothbrushing with a ≥1000 ppm concentration of F toothpaste two times per day, glass ionomer sealant and Sham LLL.

In the first consultation, the preoperative records, brushing instruction, sealants, postsealant records and the application of Sham LLL...

**Evaluations**
The evaluations will involve MIH record, simplified OHI, SCASS and VAS before the procedure. Immediately after the procedure, hypersensitivity index (SCASS/VAS) will be registered. Record of OHI and SCASS/VAS will be registered after 48 hours after and as well as 1 month after the procedure. The retention of the sealant will be evaluated after 1 month, with the CCC Sealant Evaluation System.20

A. Sealant present on all fissure system.
B. Sealant present on 50% of fissure pattern but some missing.
C. Sealant present on 50% of fissure pattern.
D. Not sealant present.

**MIH (yes or no)**
For the determination of MIH according to the European Academy of Paediatric Dentistry, the following criteria will be considered18.
► Tooth affected by demarcated opacity on occlusal or vestibular face.
► Defects may vary in shape, size and pattern.
► White, beige or brownish-yellow defects may be recognised.
► Defects may have different sizes (less than 1 mm is not registered).
► Presence of hypersensitivity.
► Teeth with atypical restorations
► Permanent teeth suspected of having been extracted due to MIH.
► Combination of characteristics above.

According to the Molar incisor hypomineralisation - Treatment need index (MIH-TNI), described by Steffen et al, Patients with MIH are classified as grade 3, presenting hypersensitivity and no visible enamel defect.¹⁹

**Simplified OHI (Greene and Vermillion)**
The Simplified OHI will be applied to the treated molars only. This secondary result aims to relate the decrease in sensitivity and the recovery of function and, therefore, the improvement in hygiene.

Analysis of soft plaque deposit²¹:
- Code 0=no deposits or pigmentation.
- Code 1=deposits covering less than one-third of the tooth surface.
- Code 2=deposits covering more than one-third but less than two-thirds.
- Code 3=deposits covering more than two-thirds of tooth surface.

The indices will be summed and divided by the number of surfaces examined to obtain the OHI.

0 = excellent  
1.2 = good  
1.3 to 3.0 = fair.  
3.1 to 6.0 = poor.

**Schiff Cold Air Sensitivity Scale**
The SCASS will be used to assess subject response to this stimulus (0=no response to the stimulus; 1=no response to the stimulus, patient considers stimulus to be painful; 2= response to stimulus, patient moves from the stimulus; 3= response to the stimulus, patient moves from the stimulus and requests immediate discontinuation of the stimulus).²²

**Visual analogue scale**
The Wong-Baker Faces-Pain Rating Scale was originally created with children for children to help them communicate about their pain. The scale is used with people ages 3 and older, facilitating communication and improving assessment, so pain management can be addressed.²³

**STATISTICAL ANALYSIS**
Descriptive statistics will first be performed taking into consideration all quantitative (mean and SD) and qualitative (absolute frequency and percentage) variables in the study. The normality of the data will then be analysed to determine the appropriate statistical tests for each set of data and the appropriate tests will be applied for each specific analysis. A 5% level of significance or corresponding p value will be adopted on all tests. All analyses will be conducted with the aid of the SAS statistical programme for Windows, V.9.1. If the data are parametric, the t-test for independent samples will be used for comparison between groups, and the comparison between times in the same group will be done with the t-test for dependent samples. If the data are non-parametric, the Mann-Whitney test will be used inter-group and the intragroup comparison between times will be done with the Wilcoxon test.

**Ethics and dissemination**
The study received approval from the Human Research Ethics Committee of *Universidade Católica do Uruguai* (UCU) (certificate number: CEUCU 220516) and it was registered with ClinicalTrials.gov. After receiving verbal and written clarifications regarding the study, individuals who agree to participate will sign a statement of informed consent. Under-aged individuals will sign a corresponding term of assent. The study will be conducted in accordance with the ethical precepts laid down in the Declaration of Helsinki (revised in Fortaleza in 2013). The treatments will be performed at the internal and external UCU clinics as well as a private dental office in the city of Montevideo, Uruguay.

**DISCUSSION**
The objective of this study will be to compare the effect of PBM associated with glass ionomer sealants in the levels of pain caused by hypersensitivity in molars with MIH, according to The MIH-TNI and the VAS Scale. It will be carried out in children between 6 and 12 years old. Pain will be measured using the SCASS and the VAS Scale. All patients will be treated with dentifrices with more than 1000 p.m. concentration F, which represents a treatment of proven efficacy for this disorder. On the other hand, glass ionomer sealants are the treatment of choice for molars in patients at risk of caries, with or without structural defects. In addition to evaluating the pain, we will evaluate the presence of biofilm in the molars studied. Hypersensitivity limit’s function and, thus, autolysis.

The hypersensitivity of molars with structural defects occurs due to the porosity of the enamel, which enables the entrance of bacteria into the dental tissue. This infiltration of bacteria causes subclinical inflammation of pulp cells, which, besides posteruptive fracture, is believed to be the main cause of this symptom. Individuals with hypersensitivity reduce brushing in the area to avoid the increase in pain. This leads to a greater accumulation of biofilm, which, together with the porosity of the area, further increases the risk of caries.³ Cavities on affected teeth emerge with an atypical pattern in terms of location and the progression velocity and can be found in patients with an otherwise low risk of caries.¹³

In practice, hypersensitivity also poses a problem for the treatment of teeth, as it makes clinical management
difficult, and the pain often determines changes in patient behaviour.\(^2\) The compressed air from the triple syringe used for inspection can cause acute pain and complicate the behavioural management of the patient. Problems with proper analgesia are also described. Composite resin-based restorative materials have adherence difficulties, which are often clinically observed by the occurrence of secondary caries and restoration flaws due to the inability to perform treatment adequately.\(^3\)

Once the diagnosis is made, the treatment of these teeth should prioritise pain relief before considering the best option for long-term viability. Different forms of treatment have been tested to diminish hypersensitivity in patients with MIH, and positive results are achieved in most cases.\(^8\)

Home hygiene is also limited by pain. Once the hypersensitivity improves, the OHI should also be improved. To analyse this, we will use Simplified Greene and Vermillion Index.

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**Contributors**

Substantial contributions to the conception: ALF and SKB. Design of the work: ALF, APTS, MLLHB, NOV, EMS, MLLG and SKB. Drafting the work: ALF, APTS, MRRSF and SKB. Revising the work: ALF, APTS, EMS, MLLG, RAMF, KPSF, LJM and SKB. Final approval of the work: ALF, KPSF, EMS, LJM and SKB. If APTS, MRFS and SKB. Revising the work: ALF, APTS, EMS, MLLHB, NOV, EMS, MLLG and SKB. Drafting the work: ALF, APTS, MRRSF and SKB. Revising the work: ALF, APTS, EMS, MLLG and SKB. If APTS, MRFS and SKB.

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**Competing interests**

None declared.

**Patient and public involvement**

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**Patient consent for publication**

Not applicable.

**Provenance and peer review**

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