

# Laser managed in the treatment of hypomineralized occlusal defects in teeth enamel affected by molar-incisor hypomineralization: A randomized controlled clinical study

# Uso do laser no tratamento dos defeitos oclusais hipomineralizados em esmalte de dentes afetados pela hipomineralização molar-incisivo: estudo clínico controlado randomizado

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#### ABSTRACT

Background: Nowadays, observed a growing rate of teeth affected by molar incisor hypomineralization (MIH). These teeth can present persistent inflammation of the pulp, increasing the dentin hypersensitivity and consequently, directly affecting the cleaning of the affected tooth and contributing to the progression of caries lesions. Aims: This study aims to compare the use of diode laser (DL) irradiation (970nm) with the application of a glass ionomer-based sealant (GIC) for the most clinically and cost-effective strategy for the management of



first permanent molars affected with MIH. Methods: This is a two-arm, parallel-group, patient randomized superiority-controlled trial, children present MIH molars will be selected and treated either with the application of DL or with the application of GIC-based sealants. Baseline and follow-up evaluations will be assessed through clinical examination and analysis of dental impressions that will be carried out of the affected teeth. The outcomes evaluated will be: 1) presence of post-eruptive breakdown and/or atypical dentin caries lesions, 2) retention rate of sealants 3) parent's satisfaction, 4) children's hypersensitivity 5) child-self-reported discomfort 6) impact on the quality of life and 7) the incremental cost-effectiveness. Evaluations will be performed by one trained evaluator after one week, and 1, 6, 12, 18, and 24 months. Multilevel statistical analyzes will be conducted to establish the ability of DL treatment compared to sealing, in joining to plausible factors associated with this efficacy. Discussion: We expect that this study contributes to the best scientific proof concerning the most cost-effective treatment for permanent molars affected with MIH.

Keywords: lasers, dental enamel hypoplasia, preventive dentistry, dental caries.

# RESUMO

Introdução: Atualmente vem-se observando aumento na incidência de dentes afetados pela hipominaralização molar-incisivo (HMI). Esses dentes podem apresentar inflamação da polpa, aumentando a hipersensibilidade e consequentemente, afetar diretamente a limpeza da região e contribuindo para a progressão de lesões de cárie. Objetivos: Este estudo tem como objetivo avaliar o emprego da irradiação do laser de diodo no tratamento de superfícies oclusais de lesões em esmalte em primeiros molares permanentes afetados com HMI em comparação com o selamento com ionômero de vidro (CIV), além de verificar a custo-eficácia desses tratamentos. Métodos: Este é um estudo randomizado, controlado de superioridade de grupos paralelos. As crianças serão selecionadas e tratadas com laser de diodo ou com selante à base de CIV. O exame clínico e moldagem dos dentes afetados serão realizados no baseline e nas consultas de reavaliações. Os desfechos avaliados serão: 1) presença de fratura pós-eruptiva e/ou lesões atípicas de cárie dentária, 2) taxa de retenção dos selantes 3) satisfação dos pais, 4) hipersensibilidade da criança 5) desconforto relatado pela criança 6) impacto na qualidade de vida e 7) custo-efetividade incremental. As avaliações serão realizadas por um avaliador treinado após uma semana, 1, 6, 12, 18 e 24 meses. Análises estatísticas multinível serão realizadas para verificar a eficácia do tratamento do laser de diodo comparada ao selamento, além de possíveis fatores associados a essa eficácia. Discussão: Esperamos que este estudo contribua para a melhor comprovação científica do tratamento mais custo-eficaz para molares permanentes acometidos pela HMI.

Palavras-chave: lasers, hipoplasia do esmalte dentário, odontologia preventive, cárie dentária.

# **1 BACKGROUND**

Currently, it has been observed a growing incidence of teeth affected by molar incisor hypomineralization (MIH), probably due to genetic distinction may interact with system factors, and improve differential diagnostic. <sup>(1)</sup> MIH is described as a qualitative alteration of dental hard tissues from the systemic origin. It can affect one or more first permanent molars, as well as can be accompanied by altered permanent incisors. The worldwide prevalence varies and values from 3.6% to 44% have been reported. <sup>(2)</sup>



Clinically, the hypomineralized enamel presents a demarcated opacity, that can present a white to yellow/brownish coloration <sup>(3)</sup>, and the defect is delimited by clear and distinct contours of healthy enamel. <sup>(4)</sup> It is also known that yellow and brown opacities present a more porous structure, <sup>(4)</sup> which results clinically in a greater risk of post-eruptive breakdown compared to white opacities. <sup>(5)</sup> In some cases, the opacity is so porous that the affected area suffers a post-eruptive breakdown during the early stages of the dental eruption, and very commonly the development of caries lesions is observed. <sup>(3, 6)</sup> Consequently, several authors have suggested a relationship between the presence of these enamel injuries and caries lesions. <sup>(5, 7-9)</sup>

Another important aspect to be considered is the hypersensitivity often reported by patients presenting MIH. The mechanism involved in this hypersensitivity is not fully understood; however, the most accepted hypothesis is related to a chronic pulpal inflammation that happens as a result of the enhanced porosity of enamel and dentin. <sup>(10)</sup> In some cases, this hypersensitivity impedes the cleaning of the affected teeth and contributes to the fast progression of caries lesions. Thus, children presenting MIH should be seen as high caries-risk patients and should be enrolled in a strict preventive program as soon as the first signs of opacities are detected, still during the early stages of first permanent molars eruption. <sup>(11)</sup> Several treatment modalities were described in the literature for the management of MIH molars and depending on the severity of the injury, defensive strategies, restorative procedures, and likewise, dental extractions can be indicated. <sup>(12)</sup> The application of pit and fissure sealants is a treatment modality often suggested in case of mild affected MIH, as it can prevent caries development and post-eruptive breakdown, as well as decrease the hypersensitivity.<sup>(13)</sup> However, it has been claimed that the porous structure of the MIH-affected teeth may negatively impact the maintenance and survival of the sealants, <sup>(14)</sup> and therefore, doubts regarding the magnitude of the benefits related to this treatment modality.

Another treatment modality that has been suggested for the prevention of caries lesions is the irradiation of dental tissues using a low intensity laser. Among the lasers that can be used for this aim, the diode laser is one suitable option, since it has been observed that it is capable of modifying the chemical-physical composition of dental tissues to an extent that an increased fluoride up take is achieved. <sup>(15)</sup> It has been also observed that the irradiation using the parameter of a wavelength of 980 nm provokes an increase in dental tissues' temperature, leading to melting and crystallizing of this structures, and therefore, resulting in surface sealing and reduced dentinal tubules. <sup>(16, 17)</sup> Additionally, the use of diode laser has been associated with decreased dentin hypersensitivity,<sup>(17, 18)</sup> which could benefit the management of MIH-molars.



Taken into consideration the fact that MIH-molars require more intensive preventive treatments, studies evaluating the magnitude and longevity, as well as cost-efficacy of these strategies are essential for clinical practice. Consequently, the objective of this study is to assess the application of diode laser irradiation for the management of first permanent molars affected by MIH compared to the application of a glass ionomer-based sealant. Also, outcomes related to the retention rate of sealants, parent's satisfaction, children's hypersensitivity, child-self-reported discomfort, influence on the quality of life, incremental cost-effectiveness, and indirect assessment of occlusal wear will be evaluated.

# **2 METHODS**

# 2.1 ETHICAL CONSIDERATIONS AND REGISTRATIONS

This protocol was written according to the guidelines of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT). The study was presented and endorsed by the Research Ethics Committee of the School of Dentistry of Ribeirão Preto of the University of São Paulo (2.683.078) and enrolled in the database for Clinical Trials Register Clinicaltrials.gov (NCT03614819).

The selection, recruitment, and care of the patients will be provided out in the dental clinic of the Pediatric department of the School of Dentistry of Ribeirão Preto of the University of São Paulo.

# 2.2 STUDY DESIGN

This is a two-arm, parallel group, subject randomized superiority controlled trial, in which the MIH-molars of the selected children's teeth will be randomly allocated to receive either with the application of diode laser or with the application of GIC-based sealants.

# 2.3 SIMPLE SIZE CALCULATION

The sample prediction was based on the issue of sealant retention. This included a superiority test based on the survival rate published for sealants applied on MIH-molars (76%) after 12 months of follow-up,<sup>(14)</sup> using a 20% difference among the groups and a significance level of 5% and a power of 80%. The tooth was adopted as the unit of analysis and it was estimated that each child would have at least one MIH- molar. The calculation of the sample revealed that 88 teeth should be selected. To this sample were added 40% to compensate for patient cluster and another20% to counterbalance for participant loss to follow-up, totaling 148 teeth.



# 2.4 PARTICIPANT SELECTION

Children between 6 and 10 years of age will be selected, and inclusion criteria the children must be with good general health, exhibiting good behavior, presenting at least one first permanent molar with the occlusal surface affected by MIH will be included. <sup>(19)</sup> In this research, only mild and moderate severity of MIH (opacities characterized by altered color or post-eruptive breakdown restricted to enamel) will be selected. <sup>(20)</sup>

Those children presenting at least one MIH-molar will be called to participate in this study. Only children presenting an informed consent endorsed by the parents/ caregiver and who consent to be part of this investigation will be included.

The children that present surfaces with severe degrees of MIH, with post-eruptive breakdown dentin involvement, will be properly treated and monitored. First permanent molars presenting opacities other than MIH, teeth restorations sealants <sup>(19)</sup> or dental caries involving dentin (ICCMS = 3) will be excluded. <sup>(21)</sup> If the same child has both teeth with and without MIH or presenting different degrees of MIH, only teeth with mild degrees of MIH on the occlusal surface will be included. In case the participants have other dental treatment needs, due to dental caries, severe it will be offered by our research team.

# 2.5 RANDOM ALLOCATION

All children will receive instructions on toothbrushing, diet, and sugar consumption at the baseline and during each evaluation consultation. Additionally, during every follow-up appointment, they will receive a new toothbrush and fluoridated toothpaste (>1000 ppm) to be used during the period of this survey. The selected participants will be allocated into one of the treatment groups (diode laser or glass ionomer-based sealant), using a random sequence generated in a specific software (<u>https://www.randomizer.org/</u>). The allocation distribution will be shared in sealed opaque envelopes, to guarantee the allocation concealment of patients.

# 2.6 DIODE LASER GROUP

Before the utilization of the diode laser (Sirolaser, Sirona Dental Systems GmbH, Bensheim, Germany), the elected tooth will be cleaned with Robson brush and prophylactic paste, washed and dried using an oil-free air syringe. The parameter used will be a wavelength of 970 nm  $\pm$  10 nm, maximum power of 7 W CW, 1mW guide beam, and 320µm optical fiber. Irradiation will be performed on the entire occlusal surface in contact mode, with the power of 0.7W and a frequency of 10 Hz for 30 seconds, producing an energy density of 87.04 J / cm2. The laser will be employed in an extensive motion completely the tooth surface, the fiber being



kept positioned perpendicular to the occlusal surface during the movement. The irradiation time will be systematized in 30 seconds. The Field Max II-TOP power meter (Coherent, Inc, USA) will be used before and after the treatments to verify that all parameters are achieved.

# 2.7 GLASS IONOMER-BASED SEALING GROUP

Before the sealant's application, the tooth will be cleaned as described in the previous group. Cotton wools rolls will be placed alongside the tooth to be treated and the occlusal surface will be pre-treated using 20% polyacrylic acid (Cavity conditioner, GC Europe, Leuven, BE) for 15 seconds. After that, the occlusal surface will be rinsed and dried using cotton pallets. New cotton rolls wools will be placed and the GIC Equia Forte, capsules (GC Europe, Leuven, Belgium) will apply, after being activated and mixed following the manufacturer's recommendations. The GIC will be firmly pressed against the first set of the material setting. After that, the G-Coat Plus (GC Europe, Leuven, Belgium) will be employed with the use of a microbrush and it will be light-cured for 20 seconds. Then, the occlusion will check using a carbon paper and in case it needs to be adjusted, a new layer of G-Coat Plus will be applied.

# 2.8 PRIMARY OUTCOME MEASUREMENTS

# 2.8.1 Post-eruptive breakdown / dental caries

Initially, two examiners will be pre-trained and calibrated by a reference examiner to perform the MIH diagnosis based on the criteria described by Ghanim (2017). <sup>(19)</sup> They will attend an expository class encompassing previous concepts of the indexes used for the exams, which will be given by the reference examiner, in addition to participating in laboratory and clinical training. The examiners responsible for the initial study inclusion exams will not be responsible for the treatment, as well as the reevaluation consultations.

Every surface will be analyzed after prior prophylaxis, using a prophylactic paste and a brush, with proper illumination and the evaluated tooth will be air-dried. The examination will be done on all dental surfaces and the exact location of each lesion will be mapped.

The main outcome evaluated will be the presence of post-eruptive breakdown/ dentin caries lesion. For that, the evaluation criteria proposed by Ghanim (2017)<sup>(19)</sup> and the ICCMS criteria will be used. <sup>(21)</sup> The ICDAS will be used for visual examination of the treated occlusal surfaces. <sup>(22)</sup>



#### 2.8.2 Sealant retention

To evaluate retention of sealants, it will be used the following scoring system: 1 - total retention; 2 - partial loss; and 3 - total loss. <sup>(23)</sup> Also, the presence of dental caries will be assessed following the ICCMS criteria. <sup>(21)</sup>

#### 2.9 SECOND OUTCOME MEASUREMENTS

#### 2.9.1 Cost of procedures and estimation of incremental cost-effectiveness ratio (ICER)

To estimate the direct expenses of the procedures, the extent used in individual consultation (initials and revaluations) will be carried into the record. Each procedure will be measured and documented in a distinct clinical report by an independent researcher, not engaged in the research. For the estimation of direct expenses, the costs of consumables and permanent materials (specs and quantity) used per procedure, <sup>(23, 24)</sup> electricity, and salaries of personnel will be counted. These amounts will be collected from the market price reached by the average of several places that markets the products in question, being modernized throughout the time of the research. Additionally, the value of equipment devaluation and electricity will be assessed.

The calculation of the salaries of personnel will be based on the time spent for each procedure, taking into consideration the average income of a dentist per hour in the state of São Paulo, which is currently US\$ 23.56 per hour worked. <sup>(25)</sup>

For the estimation of incremental cost-effectiveness ratio (ICER), the medium initial costs per group of intervention will be divided by the survival after two years.

# 2.9.2 Satisfaction with treatment

After 1 week of treatment, and then after 1, 12, and 24 months, the caregiver will be requested to answer concerning the satisfaction about the care (treatment and evaluation appointments) submitted. The patient should arrange his satisfaction using the VAS scale with indexes from 0 to 10, with 0 being the worst evaluation of treatment and 10 being the best. <sup>(26)</sup> This evaluation will not be identified by name and will also be carried out by an independent observer, not engaged in the research. This way, which will guarantee that the participants express their actual opinion.

#### 2.9.3 Discomfort referred to by children

To verify the discomfort described by the children concerning the kind of treatment received, the Wong-Baker Facial Scale <sup>(27)</sup> will be used. This scale is formed of six faces, being



the first one a happy and smiling face that gradually changes, until the last one, that is a very sad and crying face. The results are then converted to an ordinal six-point scale varying from 0 to 5. This evaluation will perform before starting the treatment and immediately after each treatment is performed, by the operator.

# 2.9.4 Dentin hypersensitivity

To assess the hypersensitivity of teeth affected by HMI, the air-jet evaluation will be performed using a triple syringe. Cotton rolls wools will be employed to isolate the neighboring teeth and the air jet will be utilized on the occlusal surface of the MIH-molar for 2 seconds with the syringe directed perpendicular to the surface and with a distance of 0.5cm from the tooth.<sup>(28)</sup> Immediately after stimulation, the patients will respond to a VAS scale, a 10-point scale ranging from 0 to 10 (0= no pain and 10 = worst pain). <sup>(26)</sup> This evaluation will be conducted before treatment, and after 1 week, and then 1, 6, 12, 18, and 24 months.

# 2.9.5 Quality of life

To estimate the impact of MIH on children's quality of life, the Child Perceptions Questionnaire 8-10 (CPQ8-10), particularly produced for children aged 8-10 years old and validated in the Portuguese language, <sup>(29)</sup> will be used. We chose to use CPQ8-10 because there is no other index to assess the influence of the quality of life in the specific age range of this study and that it is validated in the Portuguese language. Also, parents/ caregivers will also respond to the validated Portuguese version of the Parental-Caregiver Perceptions Questionnaire. <sup>(30)</sup> For this, an outside investigator will employ the survey before randomization and on after 6, 12, and 24 months of evaluation.

#### 2.9.6 Indirect assessment of occlusal wear

For quantitative assessment, the occlusal surfaces (occlusal wear), photographs, radiographic examination (digital interproximal radiography and use of radiographic positioner on both sides) and impression molding of the teeth included in the study will be performed before the treatment and after 12 and 24 months. "Triple tray" impressions will be taken using an addition-cured silicone (Examix Monophase Medium Fluid - GC) and epoxy dies (Arotec, Arotec S / A Ind. E Comércio, Cotia, SP, Brazil) will be obtained for the assessment of the wear of occlusal surfaces.<sup>(31)</sup> The obtained replicas will be analyzed in the laser confocal microscope (Olympus LEXT OLS4000, Japan) to morphologically evaluate the tooth surface and possible wear.



#### 2.9.7 Other variables

#### Variables related to the patient

Information will be collected throughout a socioeconomic survey and inquiries related to the individual features of the child, <sup>(32)</sup> such as fluoride exposure, oral hygiene habits, and consumption habits. Also, the caries activity, using the dmft/DMFT index <sup>(33)</sup> and presence of biofilm, using the debris index of the Simplified Oral Hygiene Index will be evaluated. <sup>(34)</sup>

#### Variables related to the MIH-tooth

The teeth affected by MIH that will be included in this investigation will also be evaluated regarding the following:

- Evaluation of the apparent biofilm attached on the occlusal surface, according to the following index: 0: absence of visible biofilm; 1: visible but difficult to identify biofilm - best verified after drying; 2: Visible and easily identifiable biofilm - even without drying. <sup>(35)</sup>

- Evaluation of visible biofilm attached on the vestibular surface, following the Debris Index of the Simplified Oral Hygiene index: 0: absence of visible biofilm, 1: biofilm not visible, but removed from the gingival sulcus with the periodontal probe; 2: visible biofilm after drying; 3: abundant biofilm, visible even without drying. <sup>(36)</sup>

- Evaluation of the level of eruption will be evaluated according to the following guidelines: A: not erupted or less than 1/3 of the erupted occlusal surface; B: full erupted or at least 1/3, but less than the total occlusal surface erupted. <sup>(19)</sup>

- Evaluation of lesion extension will be estimated according to the following criteria: I: less than one third of the affected tooth, II: at least 1/3 of the affected tooth, but less than 2/3, III: at least 2/3 of the affected tooth. <sup>(19)</sup>

# 2.10 FOLLOW-UP EXAMINATIONS

Participants will be re-evaluated after 1 week, and then after one, six, 12, 18, and 24 months. In case the patient presents dentin hypersensitivity (pain) or failure regarding the sealant retention (partial or total loss), the tooth will be re-treated, regardless of the group, and the costs will be properly computed. For the sealant group, costs will only be computed when sealing has been unsatisfactory in the region previously mapped with MIH. In cases when children present a dentin caries development and/ or post-eruptive breakdown with dentin involvement, in any of the follow-up appointments, he/she will be referred for radiographic examination, when necessary, and restorative treatment will be performed by the research team.



#### 2.11 STATISTICAL ANALYSIS

The inter- and intra-examiner agreement for the assessment of caries lesions and the presence of MIH will be determined by the weighted Kappa test.

The data obtained through the main outcome will be analyzed by non-parametric test and multiple Poisson regression. For the qualitative response variable (secondary outcomes), a descriptive and comparative analysis of the findings will be presented.

#### **3 DISCUSSION**

In this trial, we aim to assess the application of Diode laser irradiation on the occlusal surface of first permanent MIH-molars without post-eruptive breakdown compared with the application of a high viscosity glass ionomer-based sealant. Besides evaluating which approaches more effective in the prevention of post-eruptive breakdown/caries lesion development, we aim to elucidate the issues regarding each treatment modality is more cost-efficacy, as well as access patient-centered outcomes.<sup>(13)</sup>

Currently, although there is growing interest in the diagnosis and types of treatments for MIH, little is known about which is the most appropriate treatment for this type of enamel defect. Regarding invasive treatments, different options have been tested, <sup>(13)</sup> however, when for the non-invasive options, which propose to stop the destruction and/or loss of affected teeth, as well as reestablishing aesthetic, dental functions, and hypersensitivity treatment, few studies have been realized. <sup>(13)</sup> However, in both cases, there is still no consensus among the professionals about which treatment would be the most appropriate, it is only known that the early diagnosis, combined with the assessment of the clinical severity of MIH, dental age, and patient expectations are extremely important for the best treatment decision. <sup>(13, 37)</sup>

The choice of treatment for teeth affected by MIH must be made individually <sup>(12)(11)</sup>(11), due to chemical and structural changes in opacities caused by these defects, result in decreased mechanical properties <sup>(4)</sup> and favor the formation of caries lesions, <sup>(38)</sup> besides that, the risk of caries is an important factor that must be considered. In such cases, preventive treatment is recommended, for example, the sealing of pits and cracks with high viscosity glass ionomer. This material was the option for the control group of this study, because, in addition to being a material less sensitive to humidity, it has adhesion to dental tissues, releases fluoride, promoting remineralization of the affected region, protecting the remaining structure from caries lesions. <sup>(14)</sup>

So it is necessary to consider the prevention of the possible post-eruptive breakdown of these teeth and also, to postpone the application of restorative materials, which could lead



earlier to the repetitive restorative cycle, treatment with laser therapy was the method of choice in this study for the test group. Laser therapy must be used in operative treatment as an option to traditional methods, which interact through the emission of light energy, with biological tissues. <sup>(39)</sup> Specifically, the diode laser can decrease the inflammatory process present in the cells, by activating the sodium and potassium pumps, obliterating the dentinal tubules and, consequently, forming tertiary dentin, <sup>(18, 40)</sup> is one of the equipments most used in dentistry. With a wavelength that varies between 800-1064nm, the diode laser can be applied for soft tissue surgery, periodontal therapy, disinfection of root canals, <sup>(39)</sup> in addition to improving the sealing of the root canals.

Another possible advantage of this treatment would be the absence of problems related to adhesion, as it is known that the teeth affected by MIH have problems with adhesion of the restorative material to the dental structure. <sup>(41, 42)</sup> In addition, it is portable equipment, making it possible to carry out the treatment in less privileged populations, who do not have access to the dental office and also to control dentinal hypersensitivity, reported by many patients with MIH.

Data obtained in this investigation will increase knowledge regarding the treatment modalities available for the management of MIH-molars, a field that deserves attention. The results of this trial will likewise help public health policy determinations, dentists, and patients/parents to choose the usual clinically and cost-effective procedure to treat those teeth, as well as enable the treatment of patients that have no access to conventional dental settings.

In addition, we suppose that this study provides the most reliable scientific proof for which would be more cost-effective for the treatment of occlusal surfaces of enamel lesions in permanent molars affected with MIH.

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