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Hall Technique for the management of hypomineralized first permanent molars: A protocol of a randomized controlled trial with 3-year follow-up

Hall Technique para o manejo da hipomineralização molar incisivo: Um protocolo de um ensaio clínico randomizado com 3 anos de acompanhamento

Hall Technique para el manejo de hipomineralización molar incisivo: Um protocolo de ensayo clínico aleatório con 3 años de seguimiento

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Abstract
The aim of this clinical protocol is to describe the methodology for the evaluation of the clinical performance of Hall Technique (HT) in comparison with glass ionomer cement (GIC) restorations in first permanent molars (FPM) severely affected by molar incisor hypomineralization (MIH). This protocol is related to a two-arm, parallel group, controlled and randomized superiority trial. It will be included 92 participants, 6 to 12 years-old, presenting at least one FPM with post-eruptive enamel breakdown and/or atypical caries and/or unsatisfactory atypical restoration involving cusp and extending to at least two tooth surfaces. Two trained and calibrated dentists will select the participants and assess the outcomes. Eight experienced clinicians who work as dentists at the public oral health system will be trained to perform the interventions. The participants will be randomized into the test (HT) or the control group (GIC). The outcomes will be assessed every 6 months up to 3 years. The primary outcome is the survival rate of the restorations. Secondary outcomes include satisfaction of the participants, parents, and dentists; impact on oral heath related quality of life; self-reported discomfort during treatment; signs/symptoms of temporomandibular joint dysfunction; and cost-effectiveness. Kaplan-Meier and Cox regression analysis will be used to analyze the primary outcome. Mann-Whitney or t-test will be used to compare the secondary outcomes between groups. We expect to provide scientific evidence about the treatment approach that maximizes success rates and minimizes retreatments in severe HMI.
Keywords: Molar incisor hypomineralization; Hall technique; Stainless-steel crown; Glass ionomer cement; Permanent molar.

Resumo

O objetivo deste protocolo é descrever a metodologia para avaliação do desempenho da *Hall Technique* (HT) em comparação com restaurações de cimento ionômero de vidro (CIV) no tratamento de primeiros molares permanentes (PMP) gravemente afetados pela hipomineralização molar incisivo (HMI). Trata-se de um estudo de superioridade de dois braços, randomizado e controlado. Serão necessários 92 participantes, sendo elegíveis, escolares entre 6 e 12 anos, com pelo menos um PMP com fratura pós-eruptiva e/ou cárie atípica e/ou restauração atípica insatisfatória envolvendo cúspide e estendendo-se a, pelo menos, duas superfícies dentárias. Duas dentistas treinadas e calibradas realizarão a seleção dos participantes e a avaliação dos desfechos. Oito dentistas experientes que atuam na rede pública de saúde bucal serão treinados para realizar as intervenções. os participantes serão randomizados para o grupo teste (HT) ou controle (CIV). Os desfechos serão avaliados semestralmente por 3 anos. O desfecho primário é a taxa de sobrevivência das restaurações. Os desfechos secundários incluem satisfação dos participantes, pais e dentistas; impacto na qualidade de vida relacionada à saúde bucal; desconforto autorreferido durante o tratamento; sinais/sintomas de disfunção da articulação temporomandibular; e custo-efetividade. A análise de Kaplan-Meier e regressão de Cox serão utilizadas para analisar o desfecho primário. Dependendo do padrão de distribuição dos dados, o teste Mann-Whitney ou teste-t será utilizado para comparar os desfechos secundários entre os grupos. A expectativa é que o ensaio clínico forneça evidências científicas sobre a abordagem de tratamento para a HMI grave que maximize as taxas de sucesso e minimize os retratamentos.

Palavras-chave: Hipomineralização de incisivos molares; *Hall Technique*; Coroa em aço inoxidável; Cimento de ionômero de vidro; Molar permanente.

Resumen

El objetivo de este protocolo es describir la metodología para la evaluación de la Hall Technique (HT) en comparación con ionómero de vidrio (IV) en el tratamiento de los primeros molares permanentes (PMP) gravemente afectados por la hipomineralización molar incisiva (HMI). Se trata de un estudio de superioridad de dos brazos, aleatorizado, controlado. Se necesitarán 92 participantes, 6-12 años, con al menos un PMP con fractura post-eruptiva y/o caries atípica y/o restauración atípica insatisfactoria que involucre cúspide y se extienda, al menos, dos superficies dentales. Dos dentistas entrenadas y calibradas realizarán la selección de los participantes y la evaluación de los resultados. Ocho dentistas experimentados que trabajan en la red pública de salud bucal serán entrenados para realizar las intervenciones. Los participantes serán aleatorizados al grupo de prueba (HT) o control (IV). Los resultados serán evaluados semestralmente durante 3 años. El resultado primario es la tasa de supervivencia de las restauraciones. Los resultados secundarios incluyen la satisfacción de los participantes/padres/dentistas; impacto en la calidad de vida relacionada con la salud bucal; malestar autorreferido durante el tratamiento; signos/síntomas de disfunción de la articulación temporomandibular; y costo-efectividad. El análisis de Kaplan-Meier y la regresión de Cox se utilizarán para analizar el resultado primario. Dependiendo del patrón de distribución de los datos, se utilizará Mann-Whitney o prueba-t para comparar los resultados secundarios entre los grupos. Se espera que el ensayo clínico proporcione evidencia científica sobre el enfoque de tratamiento para la HMI grave que maximice las tasas de éxito y minimice los retratamientos.

Palabras clave: Hipomineralización de incisivos molares; *Hall Technique*; Corona de acero inoxidable; Cemento de ionómero de vidrio; Molar permanente.

1. Introduction

Molar-incisor-hypomineralization (MIH) is a developmental defect of the enamel observed clinically as demarcated opacities varying in color from creamy-whitish to yellow-brownish affecting first permanent molars (FPM) and often permanent incisors. The more porous and fragile enamel can break when exposed to masticatory forces leading to unprotected dentine and facilitating caries development (Weerheijm et al., 2001).

Although the etiology of MIH has not been completely established, it is well recognized that it has a systemic origin combined with environmental factors and genetic predisposition (Fatturi et al., 2019; Vieira & Kup, 2016) Mineralization defects affecting FPM and permanent incisors result from the occurrence of insults between birth and three to four years of age (Fatturi et al., 2019).

With an estimated global prevalence of 14.2% (Zhao et al., 2018), MIH is considered a burden not only for the patients, but also for clinicians and society at large (Schwendicke et al., 2018a). This is related to the fact that MIH is significantly associated to higher caries experience in the permanent dentition. Children with MIH not only have more caries, but also need more complex and extensive restorations (Americano et al., 2017). In addition, tooth hypersensitivity and esthetics concerns are among the reasons why MIH has a negative impact on the quality of life of children (Dantas-Neta et al., 2016).

The treatment of MIH molars depends on the severity of the condition ranging from remineralization and sealants for the mild cases to direct or indirect restorations, including preformed metal crowns, and even extraction for the more severe ones. There is no evidence to support strong recommendations for any of the available treatment options; therefore, it is recommended to evaluate each tooth specifically and consider the needs and expectations of the patients (Schwendicke et al., 2018b). Different approaches have been recommended depending not only on the severity of the hypomineralization but also on the eruption stage of the tooth and the level of compliance of the patient. In severely affected molars, direct restorations fail significantly more than indirect ones. (Weber et al., 2021). However, conventional indirect restorations require more dental tissue removal, are more time-consuming and more dependent on proper cooperation from the patients (Gaardmand et al., 2013; Linner et al., 2020). Currently, there is no scientific evidence supporting specific treatment for those cases.

Since the 50s, the stainless-steel crowns (SCC) have been suggested to restore teeth with caries and/or developmental defects (Dean & Donly, 2014). More recently, the Hall Technique (HT) (Innes et al., 2006), a simplified technique to use SCC, has gained more and more attention with high success rates in primary molars (Boyd et al., 2021; Elamin et al., 2019; Innes et al., 2015). The advantages of the Hall Technique over the conventional technique for SSC are the preservation of tooth structure because no tooth preparation is done, and the fact that local anesthesia is not necessary. Hence, the technique eliminates the use of bur and the injection, the two clinical procedures most related to dental anxiety and discomfort for the patients (Dahlander et al., 2019). Moreover, the HT is practical and less time-consuming, reducing the time in the dental chair and the level of anxiety of the children (Elamin et al., 2019). It is expected that treatments with more resistant materials will last longer preventing repetitive replacement of existing restorations. Besides that, last longer restoration could be more cost-effective and impact the quality of life of patients and their families positively. Although the efficacy of HT has been reported for the management of dental caries in primary dentition (Innes et al., 2007), to date no trials have been carried out in order to investigate the clinical performance of HT for the management of FPM with severe MIH. Therefore, aiming to fill this gap, the purpose of this study is to evaluate the clinical performance of HT as a strategy to restore FPM severely affected by enamel hypomineralization compared to glass ionomer cement (GIC) restorations.

The aim of this protocol is to describe a study that will evaluate the clinical performance of HT as a strategy to restore FPM severely affected by enamel hypomineralization compared to GIC restorations.

2. Methodology

Ethical Considerations

This study protocol was written following Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized trials of non-pharmacologic treatment (Schulz et al., 2010) and the Standard Protocol Items: Recommendations for Interventional Trials guidelines for clinical trial protocols (SPIRIT - http://www.spirit-statement.org/spirit-statement/). It was accepted by the local Research Ethics Committee, the committee of the Pedro Ernesto University Hospital – Rio de Janeiro State University (CAAE: 64306122.0.0000.5259). According to the Helsinki declaration, participation will be voluntary, and an informed consent will be obtained from guardians and participants. The protocol was registered in REBEC (RBR-4mtq8d9). Any amendments that need to be done to this protocol will be justified and submitted to the Ethics Committee and informed to REBEC.

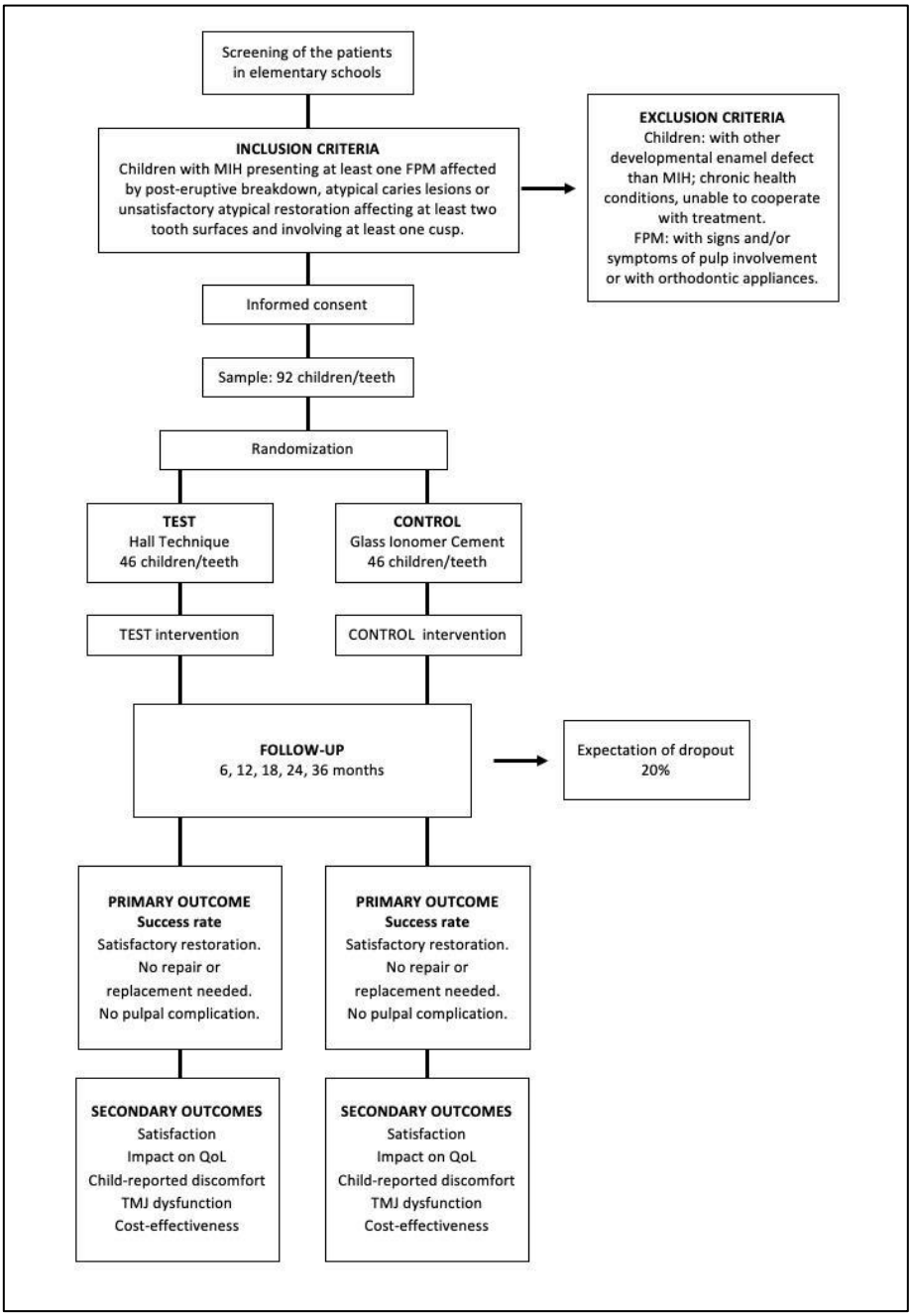
Participants and guardians will be informed that they have the right to withdraw from the study any time. In case of doubt or discomfort related to the offered treatment, the guardians of the participants will be able to contact the principal investigator any time. If participants require dental treatments other than the interventions proposed in the study, they will be offered such treatments in their best interest at no cost. Confidentiality regarding the personal data of the participants will be

guaranteed by replacing names for numbered codes in the database. Only those officially involved in the research will be authorized to handle the data.

Study Design

This is a two-arm, parallel group, patient randomized controlled, superiority trial with a 1:1 allocation ratio and 3-year follow-up. Figure 1 shows the flowchart of the study. It will be carried out in the city of Petrópolis-RJ, Brazil, in eleven public health units from the Family Health Strategy of the municipality. Petrópolis is in the southeast region of the country, in the state of Rio de Janeiro, has a population of slightly over 300,000 inhabitants. The Human Development Index is 0.745 and the population has access to artificially fluoridated water according to Brazilian regulations.

Figure 1 - Flowchart of the study protocol.



Source: Authors.

Eligibility criteria

Elementary public schools located in the area covered by the local public health system will be visited to screen participants. Children, 6 to 12 years-old, with at least one FPM affected by MIH with post-eruptive breakdown, atypical carious lesions, or unsatisfactory atypical restoration affecting at least two tooth-surfaces and involving at least one cusp will be eligible for the study. Children presenting other developmental enamel defect than MIH (*e.g.*, amelogenesis imperfecta, severe fluorosis), chronic health conditions, or unable to cooperate with treatment and FPM with signs and/or symptoms of pulp involvement or with orthodontic appliances will be excluded. Two trained and calibrated dentists will select the participants.

Sample Size

The sample size estimation was performed for a binary outcome superiority trial using the website *sealedenvelope.com* based on the primary outcome — clinical success of GIC restorations. The calculation was based on the success of the GIC restorations performed on FPM affected by reported by Fragelli et al. (2015) of 78% after one year, considering α of 5% and power of 80%. We considered a value of 20% as a superiority limit. The sample size was increased by 20% to compensate possible losses during the study. This resulted in a minimal total sample size of 92 teeth, where the sample unit is the tooth, and only one tooth will be included per child.

Randomization, allocation concealment and Blindness

The method of block randomization following a random number table generated in Microsoft Excel® for Mac (version 16.44) was used to allocate the participants into HT (test) or GIC (control) group. Eight blocks, representing the 8 dentists who will perform the interventions, will be used for the block randomization. The randomized numbers corresponding to test or control treatment will be transferred to opaque envelopes before the beginning of the clinical trial by an assistant who will be not involved in the research. The envelopes will be organized sequentially according to the random sequence. As the participants arrive at the clinic for the treatment, an assistant will pick an envelope in which there will be a written HT for test group or GIC for control group, according to the randomized sequence. In cases where the child has more than FPM eligible for inclusion in the study, only one will be selected for the study, but the other FPMs will receive treatment following the same protocol as the included tooth. In those cases, the child will have all the FPM that meet the inclusion criteria numbered. Those numbers will be written on pieces of paper, folded, and placed in an opaque envelope. An assistant will be responsible for picking one of the papers, containing the tooth number that will be included in the research. The person in charge of the statistical analysis will be blind regarding the groups. However, blindness of operators, participants, parents, and outcome examiners will not be possible due to the different nature of procedures and materials used.

Interventions

Eight experienced clinicians who work as dentists at the public oral health system will be the operators and will perform the interventions. Previously, those clinicians will be clinically trained for intervention performing at least one treatment for HT (test) or GIC (control) group. Table 1 presents the test and control treatment steps.

Table 1 - Description of the test (HT) and control (GIC) interventions. (detailed description of the composition of the products are presented as notes).

Test (HT)	**Control (GIC)**
1st appointment:	1st appointment:
• tooth prophylaxis with a rubber cup and water or tooth cleaning with manual toothbrush/ gauze swab/ cotton rolls; • measure the mesio-distal distance of the FPM with a periodontal probe for the selection of the crown; • place an orthodontic separator for Hall fitting the crown unless there are no contact points.	• tooth prophylaxis with a rubber cup and water or tooth cleaning with manual toothbrush/ gauze swab/ cotton rolls; • selective caries removal with bur and/or hand excavators until firm dentin; • rinse the cavity with wet cotton pellet; • isolate the tooth with cotton rolls and dry the cavity with cotton pellets; • mix the GIC EQUIA® FORTE (GC Corporation, Japan) capsule for 10 seconds; • fill the cavity with the GIC using a maximum working time of 1min15sec after starting the manipulation; • after 40 seconds, apply the coat with the tooth still isolated and light cure for 20 seconds; • adjustments and polishing after 2min 30sec from the start of mixing under refrigeration with appropriate abrasive drills, then apply the coat again under insulation and photoporimerize for 20sec.
2nd appointment:	
• remove the orthodontic separator; • tooth prophylaxis with a rubber cup and water or tooth cleaning with manual toothbrush/ gauze swab/ cotton rolls; • select the correct crown size (PermaCrown - KidsCrown; Shinhung Co., South Korea). The crown should covers all the cusps and approaches the contact points, with a slight feeling of "spring back." The smallest size of crown which fits well will be choosen; • do the adjustments in the crown: reduce the occluso-cervical height using a metal scissors, polish the sharp edges with a high-speed handpiece and polishing rotating stone for metal, redirect of the edges with an orthodontic curved plier to obtain a proper cervical contour; verify the crown adaptation and occlusion; • rinse the internal surface of the crown, the tooth with water and dry and isolate the tooth with cotton rolls; • mix the GIC Meron (VOCO, Germany) using the recommended powder: liquid ratio (1 scoop : 1 drop) and load the crown with GIC (at least two thirds full); • place the crown on the tooth and seat it in place by finger pressure and/or ask the child to bite it into place. • check the crown position as soon as it is fitted. If necessary, correct the crown position; • remove excess of GIC with gauze swab or cotton rolls and by flossing between the contacts.	

HT: Hall Technique; GIC: glass ionomer cement; FPM: first permanent molar. Note: the indication for topical and/or local anesthesia in both test and control groups will be done based on the dentist's judgement. When necessary, the topical anesthesia will be performed with 2% benzocaine and the local anesthesia with infiltrative or block anesthesia using lidocaine with epinephrine 1:100.000. This procedure will be registered in the patient's form.

Training of the operators

Operators will be trained by an experienced pediatric dentist on how to perform the interventions. First, a theoretical training (8 hours) will be based on detailed presentation of the interventions step by step and the manufacturer's instructions on how to use the products. Then, a practical training on models will be followed (4 hours) by a practical training on patients (4 hours). Each dentist will perform one HT intervention and one GIC intervention in patients.

Training of the examiners

Theoretical and practical training about MIH, caries, and plaque/gingival indices will be performed by an experienced examiner. For MIH, a calibration exercise will be done with 40 clinical photographs to assess the level of agreement in MIH diagnosis. After 3 weeks, photographs will be re-analyzed. For caries, a practical training was done during the examination of five children. Then, 20 children will be examined by each examiner independently and re-examined 2 weeks later. A kappa value

≥ 0.70 will be considered a satisfactory intra-examiner and inter-examiner agreement. For plaque and gingival indices only, training will be performed.

Assessment of baseline data and outcomes

The two independent trained and calibrated examiners will assess the baseline data (before treatment) and the outcomes every 6 months after treatment, during a total follow-up of 3 years. MIH, dental caries, plaque, and gingival status will be assessed clinically in the school setting under artificial light, using dental mirror, probe, and cotton rolls to control moisture. Two trained and calibrated examiners will perform the baseline examinations. First, plaque and gingival indices will be evaluated. Then participants will have their teeth brushed, and MIH and dental caries will be assessed. MIH will be assessed according to the criteria proposed by Ghanim et al. (2017) (Ghanim et al., 2017), dental caries following dmft/DMFT index (Petersen, 2003), and plaque and gingival indices according to Löe (1967) (Löe, 1967). Table 2 presents the description of the scores for each of the conditions assessed.

Table 2 - Description of the indices used to assess molar incisor hypomineralization, dental caries, plaque index, and gingival index in the baseline.

Scores		Description of the criteria
MIH (Ghanim et al. 2017)	21	white-creamy opacity
	22	yellow-brownish opacity
	3	post-eruptive breakdown
	4	atypical restoration
	5	atypical caries
	6	tooth lost due to MIH
Dental caries	d/D	decayed
(Petersen, 2013)	e/M	extraction indicated/missing
	f/F	filled
Plaque index (PI)*	0	no plaque
(Löe, 1967)	1	a film of plaque recognized with the probe
	2	moderate plaque seen by naked eye
	3	abundance of plaque
Gingival index (GI)*	0	normal gingiva
(Löe, 1967)	1	mild inflammation, no bleeding on probing
	2	moderate inflammation, bleeding on probing
	3	severe inflammation, spontaneous bleeding

* PI and GI will consider six reference tooth surfaces: the buccal surface of 16,11, and 26 and the lingual surface of 36, 31, and 46. The individual score will result from the sum of the scores assigned to each tooth surface divided per 6.

Primary outcome: clinical performance of treatments

Each treated tooth will be classified based on the criteria described in Table 3 which were adapted from Innes et al. (2006) (Innes et al., 2006). Satisfactory restorations/crowns will be considered “success”, while the presence of minor and/or major failures will be considered “failures”. The primary outcome will be assessed every six months until the 36-month follow-up.

Table 3 - Clinical criteria used to assess the success of the treatment (adapted from Innes et al. 2006).

Success	Satisfactory restoration/crown, no intervention needed (absence of marginal failure, breakdown, or wear; crown still present). Absence of signs and/or symptoms of pulpal pathology (abscess, fistula and/or espontaneous pain).
Failure	
Minor	Unsatisfactory restoration/crown represented by minor marginal failure, breakdown, or wear; loosing crown. Repair of the restoration/crown is needed. Absence of signs and/or symptoms of irreversible pulpal pathology (abscess, fistula and/or espontaneous pain).
Intermediate	Unsatisfactory restoration represented by major marginal failure, breakdown, wear, or total lost (filling or crown). Replacement of the restoration/crown is needed. Absence of signs and/or symptoms of irreversible pulpal pathology (abscess, fistula and/or espontaneous pain).
Major	Unsatisfactory restoration represented by major marginal failure, breakdown, wear, or total lost (filling or crown) that is impossible to replace and/or signs and/or symptoms of pulpal complication are detected (abscess, fistula and/or espontaneous pain).

Source: Authors.

Secondary outcomes

Participants', parents', and dentists' satisfaction

The satisfaction of participants, parents and dentists will be evaluated through a questionnaire based on previous studies (Thilander et al., 2002). A structured interview comprising questions about functional and esthetic aspects of the treatments will be done at the first follow-up appointment, 6 months after the treatment. In the final part of the structured interview, participants and parents will be asked about their overall satisfaction with the treatment and if they would choose the same treatment if once again it were offered. A similar question will be done to the dentist to know if he/she would indicate the same treatment if he/she had the chance to do it again. Table 4 summarizes the questions.

Table 4 - Questionnaire about satisfaction with the treatment (based on Yanover et al. 2021).

Esthetics	Children/Parents		
	Do you think your tooth/your child's tooth is beautiful after the treatment?	0	No, I didn't like the way it looks.
		1	It is acceptable, but it could be more beautiful.
		2	Yes, I think it is beautiful.
	Dentists		
	Are you satisfied with the esthetics of the treatment?	0	No, the esthetics is very poor.
		1	It is acceptable, but it would be better if the esthetics could be improved.
		2	Yes, the esthetics is good.
Durability	Children/Parents		
	How does the restoration look to you?	0	It appears defective with large cracks, fracture, or loose.
		1	It appears defective with small cracks, fracture.
		2	It appears intact with no cracks or fracture.
	Dentists		
	How do evaluate the restoration?	0	It has an unsatisfactory shape and/or contour, and/or large marginal defect or fracture.
		1	It has an unsatisfactory shape and/or contour, and/or small marginal defect or fracture.
		2	It has a satisfactory anatomical shape, good contour, no marginal defect, or fracture.
Overall satisfaction	Children/Parents		
	Would you choose the same treatment if once again it was offered?	0	No.
		1	Yes.
	Would you recommend this treatment for friend/friend's child?	0	No.
		1	Yes.
	Dentists		
	Overall, how do evaluate the treatment?	0	It is not effective.
		1	It is effective.
	Would you indicate the same treatment for a similar tooth?	0	No.
		1	Yes.

Source: Authors.

Impact of the treatment in the oral related quality of life

The impact of the treatment in the quality of life will be assessed using the self-perception questionnaire about oral health proposed for children with molar-incisor hypomineralization (Yanover et al., 2021). The questionnaire will be applied to the participants in the baseline and 6 months after treatment. The mean score obtained with the questionnaire before treatment will be compared with the mean score after treatment.

Self-reported discomfort

The self-reported discomfort will be assessed using the visual analogue scale Wong-Baker FACES Pain Rating Scale (Wong & Baker 1988). This is an ordinal six-point scale ranging from 0 to 5, and score 0 shows a smiling face, indicating no discomfort, whereas a score of 5 shows a crying and sad face, indicating great discomfort. Immediately after the end of treatment, when the child is out of the treating room, a trained dental assistant will ask the child to point which face better depicts what he/she experienced during the treatment.

Time required for the treatment

The time required for the test and control treatments will be recorded with a chronometer and registered in minutes. For the test intervention (HT), two appointments will be necessary. In the first appointment, the chronometer will be initiated when the child is in the dental chair with his/her mouth open and the dentist has the orthodontic rubber ring in hands. When the orthodontic rubber ring is in place and the dentist says the child can close his/her mouth, the chronometer will be ended. In the second appointment, the chronometer will be initiated when the child is in the dental chair with his/her mouth open and the dentist has the probe to remove the orthodontic rubber ring in hands. When the crown is cemented, excess was removed, and the dentist says the child can close his/her mouth, the chronometer will be ended. For the control intervention (GIC), only one appointment is necessary. The chronometer will be initiated when the child is in the dental chair with his/her mouth open and the dentist has the dental mirror and hand excavator in hands. When the restoration is finished and the dentist says the child can close his/her mouth, the chronometer will be ended.

Signs and/or symptoms of temporomandibular joint (TMJ) dysfunction

The criteria of Lövgren et al, 2016 (Lövgren et al., 2016) will be used to evaluate signs and symptoms of temporomandicular joint (TMJ) dysfunction. Participants will be asked to answer ‘yes’ or ‘no’ for each of the following questions: 1- “Did you feel pain on the side of your head (points to the temporal bone), in the cheek (points to the masseter), in that bone (points to the base of the jaw) or near the ear (points to the TMJ) in the last days?"; 2- “When you 'open your mouth or chew' you felt pain on the side of your head (points to the temporal bone), in the cheek (points to the masseter), in that bone (points to the base of the jaw) or near the ear (points to the TMJ) in the last days?"; 3- “Have you had difficulty opening or closing your mouth in the last few days?” Assessment will be carried out before treatment and every 6 months until the 3-year follow-up.

Cost-effectiveness

An incremental cost-effectiveness ratio (ICER) will be calculated. First, the average cost per treatment will be quantified for both HT and GIC restorations. Effectiveness will be measured by percentage of treatment survival. A microcosting will be carried out to estimate the direct costs of each treatment modality. This will include the capital costs of all equipment and instruments, materials and overheads, and the costs of time and labor. Also, the time expend to perform each one of the treatments will be used in this calculation. The initial cost of treatments will be calculated, taking into account the parameters described in

the Table 5. The initial costs of treatments will be calculated by summing the expenses of capital cost, material cost and labor cost. Finally, the ICER will be generated per treatment group by dividing the average initial cost by the survival after 3 years.

Table 5 - Parameters considered to calculate the costs of treatments.

Capital costs	Fixed cost of equipment and instruments, such as autoclave and examination kits. For analysis a lifespan of a dental instrument of approximately 3 years or 1095 days (constant depreciation rate) will be considered.
Materials costs	Supplies such as gloves, masks, articulating paper, restorative material and PMCs. Their accumulated costs will be estimated per restoration.
Labor costs	Salaries of dentists and dental assistants will be calculated using the top point in their Brazilian Public health Service salary scales for the city in which the treatment is being provided. The labor cost per day will be divided by the number of restorations/ PMCs placed per day.

Source: Authors.

Adverse events

Serious and nonserious adverse events will be assessed 24h after the interventions and at every follow-up visit. Twenty-four hours after the intervention, using a structured interview, an assistant will call the participants' guardians and make questions about post-operative pain and any other sign or symptom of potential complications, like soft tissue trauma due to local anesthesia, tooth pain or swelling. If necessary, the guardian will be asked to take his/her child for a visit to the dentist for a clinical evaluation and appropriate treatment. Then, the same questions will be done at every follow-up visit by the examiners.

Statistical analysis

Demographic data and characteristics of the participants/teeth assessed in the baseline will be described using mean and standard deviation for quantitative variables and percentages for qualitative variables. For the primary outcome, a Kaplan-Meier survival analysis and the log-rank test will be used in order to verify the survival rate of treatments. To evaluate the association between the outcome and the independent variables (gender, age, MIH severity, dmft/DMFT, plaque and gingival indices), a Cox regression test will be applied. For the secondary outcomes, first a Kolmogorov-Smirnov and Levene tests will be used to consider the normality distribution and homoscedasticity of the data. Depending on the data distribution, the Mann-Whitney test or independent *t* test will be applied to compare the degrees of discomfort, satisfaction of the participants, parents, and dentists regarding the treatments, plaque index and gingival health, and the difference in mean scores of oral health related quality of life between the two groups of intervention. The differences between the mean scores of the oral related quality of life questionnaire obtained at 6 months and at baseline will be calculated and tested, using a paired *t* test. For cost-effectiveness analysis, the primary measure will be the survival rate of treatments. The ICER will be generated per treatment group by dividing the average initial cost by the survival after 3 years, and the following formula will be used: ICER = ($cost_t$-effectiveness) / ($cost_c$-effectiveness), where *t*= test and *c*=control. Statistical significance will be set at $p < 0.05$ for all tests.

3. Discussion

Patients with MIH represent one of the major challenges in contemporary Pediatric Dentistry, especially the more severe cases where FPM present extensive enamel breakdown often combined with caries lesion. The scenario involves young patients with partially erupted FPM, usually presenting hypersensitivity, who need extensive and complex restorations involving multiple tooth surfaces and cusps (Americano et al., 2016). In addition to the complex factors related to teeth, these children may experience dental pain due to hypersensitivity or exposed dentin (Linner et al., 2021) and, although there are controversies, they may experience increased dental anxiety and fear (Reis et al., 2023). According to the principles of operative dentistry, the

survival rate of restorations involving two or more tooth surfaces and extending to cusps will be increased if indirect techniques are employed (Conceição, 2018). However, tooth preparation for indirect restorations requires enough tissue removal to guarantee a proper thickness of the restoration, otherwise the resistance of the material is compromised (Hamburger et al., 2014). It might be a challenge when dealing with young hypersensitive permanent molars that have large pulp chamber. Besides that, the molars are not fully erupted and the occlusion with the opposite tooth is not established yet. The stainless-steel crown used according to the HT protocol was selected as the test treatment in this clinical trial for three main reasons. First, because it is an indirect restoration that covers the tooth completely protecting against continuous enamel breakdown. Second, because no tooth preparation is needed enabling to preserve tooth structure. Third, because it is practical and comfortable for the patient. The HT has been used with high rate of success in primary molars (Boyd et al., 2021; Elamin et al., 2019; Innes et al., 2006; Innes et al., 2015) . In a case series study, the HT was an effective restorative option for FPM severely affected by MIH. Both patients and parents were satisfied with the treatment and no complications were observed along the first six months of follow up. The open bite caused by the placement of the crowns with no tooth preparation was reduced or totally closed in the first months after the treatment (Guerra et al., 2021). Other favorable experiences adapting the HT for MIH molars have been reported (Farias et al. 2022; Grizzo et al. 2022). The present protocol aims to evaluate if the effectiveness of the HT observed in a low number of patients may be proved in a larger scale in a study designed as a randomized controlled clinical trial.

For the control treatment, we opted for GIC, acknowledging that while it may not typically be recommended for extensive restorations, our decision was based on a recent survey. This survey evaluated the treatment options available for severely affected FPM due to MIH within the public oral health system in Brazil. Findings revealed that among the available options, GIC was the most commonly used restorative material by dentists. Notably, indirect options like stainless steel or casting crowns were unavailable in the primary public dental care system. When presented with a clinical case involving MIH affected FPM with severe enamel breakdown involving cusps and caries, nearly 70% of surveyed dentists indicated GIC as their choice for restoration. In the same survey, the dentists also reported a high failure rate of restorations placed in MIH affected molars (Gomes, 2022). Hence, the present clinical trial intends to evaluate the stainless-steel crowns, placed according to the HT protocol, as an alternative to GIC restorations. Although two clinical studies reported considerable high survival rates of GIC restorations in MIH molars, the follow-up was relatively short. Additionally, the higher risk of failure was related to the more extensive restorations, involving multiple tooth surfaces and/ or cusps (Fragelli et al., 2015; Grossi et al., 2018).

The primary outcome was defined as the survival rate of the restorations, as it represents a robust outcome often used to measure the durability of a proposed treatment over a period of time. Nevertheless, we will include in our analysis patient and tooth-related factors that can possibly influence the primary outcome, which may help elucidating the factors possibly contributing for treatment failure (Demarco et al. 2012). While the primary outcome of the current clinical trial was on assessing the treatment's clinical performance from a technical standpoint in operative dentistry, it is important to highlight that patient-centered outcomes were also included as part of the assessment. First, we intend to assess the treatment's impact on the patient's quality of life. To achieve this, a pre- and post-treatment questionnaire about oral health related quality of life will be administered to participants. Additionally, a visual analogue pain scale will be used to prompt participants to express their comfort levels throughout the procedure. Lastly, the overall satisfaction with the treatment will be assessed administering a questionnaire to both the participants and their parents. Clinical outcomes, such as the survival rate of the restorations, need to be paired with patient-centered outcomes, assessing how much the treatment enhanced the patient's quality of life. This combined approach is crucial to substantiate treatment decisions.

The HT has been advocated for its practicality, requiring less time comparing with traditional dental restorations. As a non-invasive procedure, it is supposed to offer more comfort to patients. Among others advantages, local anesthesia is rarely required (Evans & Innes, 2010). One disadvantage, however, is the open bite that results from the cementation of the crown with

no prior tooth preparation. Nonetheless, the open bite is transitory and tends to resolve in the subsequent months through natural adjustment of the occlusion (Boyd et al., 2021; Elamin et al., 2019; Innes et al., 2006; Innes et al., 2015). Despite recent literature indicating no clinically relevant association between dental occlusion or occlusal interferences and temporomandibular disorder (TMD) (Manfredini et al., 2017), we chose to use the 3Q/TMD screening questionnaire before and after the treatment. Our aim is to confirm that the sudden change in occlusion has no adverse consequences.

Besides being clinically effective and meeting patient expectations, an ideal treatment should be cost-effective. For this reason, the current clinical trial will assess capital, material, and labor costs to calculate the incremental cost-effectiveness ratio for both test and control treatments. The calculation will consider potential retreatments along the follow-up period.

We hope that the results of the current clinical trial may be useful in supporting new guidelines with evidence to construct a decision tree for restorative treatment for MIH molars. Children severely affected by MIH have been one of the most challenging clinical conditions in Pediatric Dentistry.

4. Conclusion

The present protocol intends to provide scientific evidence to choose based on better clinical performance HT or GIC restorations as a strategy to restore FPM severely affected by molar incisor hypomineralization. This knowledge could support policy makers and clinicians to adopt an effective treatment to children with this condition.

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