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Pulp vitality of primary molars with deep caries treated with ART restorations: 2-year RCT

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Abstract: The aim of this study was to compare the pulp vitality of primary teeth with deep caries treated with two restorative techniques. The restoration survival rate was also evaluated as a secondary outcome. Children aged from 4 to 8 years with at least one deep carious lesion in molars were selected at the Ibirapuera University dental clinic. One hundred and eight deciduous molars were allocated into two groups: (1) restoration with calcium hydroxide cement lining followed by filling with high-viscosity glass ionomer cement (CHC+HVGIC) or (2) restoration with HVGIC. Pulp vitality and restoration survival were evaluated at 6, 12, and 24 months. Intent-to-treat analysis was used for pulp vitality, and survival analysis was performed with the Kaplan-Meier method (α=5%). Results: At 24 months, 86 restorations were evaluated, and 91 were evaluated at least once during the study. There was no significant difference between the restorative treatments regarding pulp vitality (CHC +HVGIC=70% and HVGIC=68.5%) (OR=1.091; CI95%=0.481-2.475). However, HVGIC (73%) restorations showed a higher survival rate than CHC+HVGIC (50%) (p=0.021). Thus, it can conclude that deep caries in primary molars should be restored with HVGIC, since the technique results in similar pulp vitality to the CHC +HVGIC, but with a higher restoration survival rate.

Keywords: Calcium Hydroxide; Dental Pulp Capping; Tooth, Deciduous; Glass Ionomer Cements; Dental caries.

Introduction

The Global Burden of Disease study indicates dental caries as one of the ten most prevalent health problems affecting children.[1] Dental caries, especially cavitated lesions in dentin, have a negative impact on oral-health related quality of life in children and their families.[2] Thus, the management of these lesions should be a priority for dental care providers, especially in public health centers.

Systematic reviews have supported minimal intervention options for the treatment of cavitated carious lesions showing satisfactory results in primary teeth.[3-8] There is an evidence-based consensus suggesting that active cavitated carious lesions in dentin should be managed with selective caries tissue removal.[9] More invasive treatment options should be avoided in deep caries to prevent accidental pulp exposure.[8,9]

Leaving a layer of soft dentine over the pulp seems to allow tissue remineralization and the formation of tertiary dentin in order to protect the dentin-pulp complex.[10] However, the use of a biocompatible material as a liner is still advocated by dentists as a treatment for deep caries to induce the formation of reactionary dentin. Different materials have shown efficacy in arresting the caries process, including inert materials[11] as long as the restoration provides a good seal at the tooth-restoration interface.[12,13]

The use of high-viscosity glass ionomer cement (HVGIC) to restore deep caries based on the atraumatic restorative treatment (ART) approach (using hand instruments to open the small cavities, and for selective caries removal) has been scarcely evaluated in clinical trials. The confirmation of this technique as an efficient treatment would provide an easier option for deep caries management by pediatric dentists.

Furthermore, a systematic review on this topic has stated that the use of calcium hydroxide cement (CHC) as a liner in deep caries lesions appears unnecessary. However, the level of evidence was of moderate to very low quality; thus, it has been suggested that further well-designed, randomized, and controlled clinical trials are necessary to provide stronger recommendations.[10] The authors emphasized that the inclusion of other studies in the meta-analysis could improve the confidence in the effect size estimate as well as change the estimate.[10]

As studies with hard outcomes, such as pulp vitality, are recommended, this prospective randomized controlled study aimed to compare the pulp vitality of two restorative options for the management of deep caries in primary teeth. The restoration survival rate was also evaluated as a secondary outcome.

Methodology

Trial design, ethical approval and deviations from protocol

This study was designed as a two-arm parallel group (1:1 allocation rate), controlled, non-inferiority, randomized, double-blind (patients and examiner) clinical trial with a 2-year follow-up. The study protocol was approved by the ethics committee of the Faculty of Dentistry – Ibirapuera University (#1.670.059), registered at the clinical studies database (ClinicalTrials.gov registration number NCT02903979), and published.[14] It was planned a revaluation at 18 months. However, it was not performed. The other outcomes foreseen in the protocol will be published later. This paper was reported according to the Consolidated Standards of Reporting Trials (CONSORT 2010) guideline[15]. Written informed consent was obtained from all legal guardians of participants. Children also agreed in participating by nodding their heads.

Sample size

The sample size calculation was based on the primary outcome, pulp vitality. Since that there are no previous studies evaluating the pulp vitality from ART restorations using CHC, we considered data from indirect pulp treatment. A 94% expected success rate was considered for pulp vitality using calcium hydroxide cement as a lining material in 12 to 29 months of follow-up[16]. A clinically significant difference between groups of 15%, a significant level of 0.05, and a power of 0.80 were used. Considering a one-tailed test for non-inferiority trials, 20% of possible sample loss, and an extra 40% due to the cluster design (teeth as unit of analysis), a final number of 54 teeth per group and 108 total teeth was reached.

Participants

Children aged from 4 to 8 years seeking dental treatment at the Clinic of Pediatric Dentistry of the Ibirapuera University, Sao Paulo, Brazil were screened with a wooden spatula under natural light. Potentially eligible children were referred for a clinical examination by an examiner involved in the study. Children with at least one deciduous molar with a deep caries on the occlusal/occlusoproximal surfaces were included. Deep caries were defined as those that radiographically involving the inner third of the dentine. Patients with special needs, systemic conditions that could influence the oral cavity, or using orthodontic devices were excluded. We also excluded teeth that were restored, sealed, with enamel developmental defects, pulp exposure, spontaneous pain, mobility, swelling, fistula, or mobility incompatible with the root resorption stage.

An initial bite-wing radiograph was obtained to confirm the lesion depth and to exclude a possible pulp involvement.

Study groups

All volunteers who met the eligibility criteria were randomly divided into two groups: a) restoration with calcium hydroxide cement lining and high-viscosity glass ionomer cement (CHC+HVGIC) filling and b) restoration with HVGIC filling.

Randomization and allocation concealment

Teeth were allocated in two parallels arms: HVGIC and CHC+HVGIC groups. The random sequence generation was performed by an external researcher considering the type of cavity – occlusal or occlusoproximal surfaces – as strata, in blocks of 4 and 6, using www.sealedenveloped.com web site. The group assignment was concealed in individual opaque sealed envelopes that were opened by dental assistants after the selective caries removal and immediately before the restorative procedures.

Interventions

The operators were previously trained for theoretical and practical aspects to ensure the standardization of the clinical procedures and minimize variations. The training included three hours of theoretical lectures and pre-clinical activities for both HVGIC and CHC+HVGIC restorations. Two trained operators performed the restorations according to group assignment at the Clinic of Pediatric Dentistry of the Ibirapuera University.

Selective carious tissue removal to soft dentin from pulp wall was performed using a sharp spoon excavator compatible with cavity size, under relative isolation with cotton rolls. The carious tissue was completely removed in peripheral enamel and in dentin-enamel junction until reaching sound substrate. A metal matrix was used in occlusoproximal cavities for filling. Cavities filled with HVGIC were etched with polyacrylic acid for 10 sec, followed by washing and drying with cotton pellets. HVGIC (Fuji IX; GC Corporation, Tokyo, JP) was mixed according to the manufacturer's instructions and inserted into the cavity with a spatula, and gently pressed with a finger on the occlusal surface using petroleum jelly to avoid sticking. For teeth allocated to the CHC+HVGIC group, a thin layer of a hydroxide calcium cement (Hydro C; Dentsply Sirona, USA) was applied on pulp/axial walls following the manufacturer's instructions before filling with HVGIC. HVGIC restoration was performed as previously mentioned to HVGIC group. Finally, the occlusion was checked for interferences with carbon paper, and then the restoration surfaces were protected with petroleum jelly.

All participants and their legal guardians were instructed regarding oral hygiene with fluoride toothpaste at least 2 to 3 times a day. Participants with other dental needs were treated by members of CEPECO collaborative group according to the decision-making diagram previously proposed.[14]

Follow-up and outcome measures

Patients were reminded of their follow-up visits by a phone call or letter. Participants who could not be reached were considered lost to follow-up.

Participants were scheduled for clinical examination at 6, 12, and 24 months after the restorative treatments. Two experienced, trained, and calibrated examiners (TKT and ACVMM) conducted the clinical and radiographic evaluations, as well as the question about pain. The training consisted of 3-h theoretical lectures with photograph evaluations. The calibration process consisted of the clinical evaluation of children with dental conditions similar to those of the trial to check inter-rater reliability of outcomes assessment according to the agreed evaluation criteria. Intra-rater reliability was checked by 20% of the sample size that was re-evaluated after one month up to the first evaluation. The examiners were blinded to the intervention and were not involved in group allocation or restorative procedures.

The primary outcome was the success rate of pulp vitality after two years of follow-up. The survival of restorations was considered a secondary outcome.

Outcomes

Pulp vitality was evaluated considering the presence of pulp involvement, fistula formation and abscess, associated with radiographic evaluation. Success was defined as the presence of pulp vitality,

even though there were minor failures in the restoration, which could be resolved by replacing or repairing the restoration. Failure was defined as visible pulp involvement, fistula, and abscess, with pain and pathological mobility in the clinical assessment. Teeth that presented furcation involvement or periapical lesions, internal or external root resorption in the radiographic exam were also considered a failure.[17]

Survival of restorations was evaluated using the criteria proposed by Frencken et al.[18] for occlusal restorations, and the criteria proposed by Roeleveld et al.[19] for occluso-proximal restorations. Occlusal restorations were considered a success if rated a score of 0 (present, good), 1 (present, slight defect at the margin and/or wear of the surface of less than 0.5 mm deep; no repair needed), or 7 (present, gradual wear and tear over larger parts of the restoration but less than 0.5 mm at the deepest point; no repair needed). Occlusoproximal restorations were considered success if rated a score of 00 (restoration is present, good) or 10 (restoration is present, slight defect at the margin and/or wear of the surface; < 0.5 mm in depth, no reparation needed).

Blinding

Blinding of operators was not possible due to the evident differences between the restorative interventions. However, the participants and the examiners were blinded. Blinding of examiners was possible as restorations from both groups were clinically similar.

Statistical analysis

A researcher not directly involved in the study performed the statistical analysis of the data. The chi-square test was used to compare the distribution of the success and failure rate of pulp vitality according to the type of cavity at 12 and 24 months for each group. The intra-rater and the inter-rater reproducibility for outcomes evaluation were calculated using the weighted kappa test.

Intention-to-treat (ITT) analysis was used for the primary outcome. Logistic regression was used to compare pulp vitality between groups. Odds ratios (OR) and 95% confidence intervals (CI) were calculated. Statistical analysis was carried out using SPSS statistical software (Chicago, USA).

Kaplan-Meier analysis was used to estimate the survival of restorations. Patients evaluated at least once during the study were included in the analysis. The log-rank test was used to evaluate differences between the survival curves. Annual failure rate was also calculated.[20] To assess the association between restoration survival and explanatory variables, the multivariate Cox regression model with shared fragility was used. The final model included the variables with $p \leq 0.05$ in the univariate analysis. Hazard ratios (HR) and 95%CI were calculated. Statistical analysis was performed using survival and survimener packages of the RStudio, version 1.1.45 statistical software, version 4.0.2 (R Core Team, 2012, Vienna, Austria). The significance level was set as 5% for all analyses.

Results

The Kappa value for inter-rater reliability was 0.91, and intra-rater reliability was 0.87. One hundred and eight teeth were randomly allocated to receive HVGIC (n = 54) or CHC+HVGIC (n = 54). Children were enrolled from November 2016 to April 2018. The final follow-up evaluation was performed in March 2020. At 2-year follow up, 86 teeth were assessed, and 91 were evaluated at least once during the study. The final drop-out rate was 20%, and the number of participants at the beginning and at end of the study was similar between the groups (p = 0.872). Figure 1 shows the flow chart of participants throughout the study phases.

The baseline characteristics of participants, according to allocated group, are shown in Table 1. Most were girls (54.8%), 4–5-year-olds (59.3%), presented high caries experience (89.9%), and poor oral hygiene (56.5%).

Table 2 shows the results for pulp vitality. The per protocol analysis of the data was performed, but it not significantly differed from ITT analysis. For this reason, only ITT results were displayed. The pulp vitality success rate of the HVGIC and CHC+HVGIC groups were, respectively, 68.5% and 70%, after 2 years (p = 0.835). The distribution of success and failure rate of pulp vitality according to the type of cavity

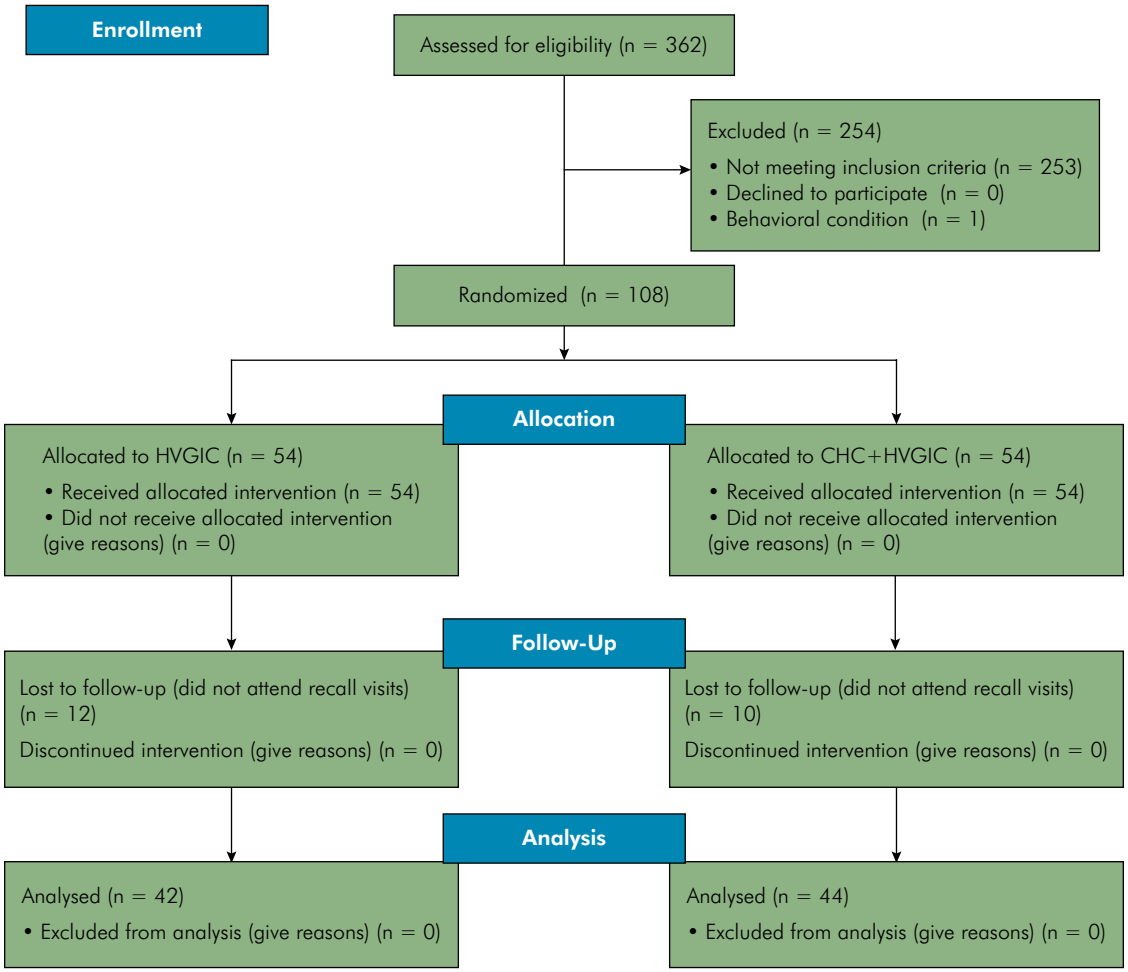

Figure 1. Flow chart of participants through the study phases.

at 12 and 24 months for both groups are displayed in Table 3. For HVGIC group, the distribution of failures was similar between the occlusal and occlusoproximal surfaces at 12 ($p = 1.0$) and 24 months ($p = 0.085$). Conversely, for CHC+HVGIC group, a higher failure rate was observed for occlusoproximal surface in both 12 ($p = 0.018$) and 24 months ($p = 0.040$).

On the other hand, the HVGIC group showed a higher restoration survival rate compared to CHC+HVGIC ($p = 0.021$). The Kaplan-Meier curve is shown in Figure 2. The survival rate of HVGIC and CHC+HVGIC were, respectively, 73.3% and 50%, after 2 years. The annual failure rate was 13% for HVGIC and 20.3% for CHC+HVGIC. Table 4 shows the results of the Cox regression analysis. Only the treatment variable presented a $p < 0.20$. Thus, the adjusted analysis was not performed. Teeth treated with HVGIC had 65% less chance of failure than those treated with CHC+HVGIC.

No harm or unintended effects were verified in both groups.

Discussion

The management of deep caries is still a challenge for dentists and there is no robust evidence on whether or not the use cavity lining is required. As easier and effective techniques could be helpful, especially for pediatric patients, this study compared the long-term pulp vitality of primary teeth with deep caries managed by two restorative options. Teeth restored with HVGIC without cavity lining, following the ART approach, showed similar results to teeth restored with CHC cavity lining and HVGIC filling.

Table 1. Baseline characteristics of participants included into the study.

Characteristics	CHC+HVGIC	HVGIC
	n (%)	n (%)
Sex		
Female	28 (51.9%)	29 (53.7%)
Male	26 (48.1%)	25 (46.3%)
Age		
4–5 years old	25 (46.3%)	19 (35.2%)
6–8 years old	29 (53.7%)	35 (64.8%)
Caries experience		
ceo-d<3	6 (11.1%)	5 (9.3%)
ceo-d≥3	48 (88.9%)	49 (90.7%)
Oral Hygiene*		
Good: 0.0–0.6	11 (20.4%)	8 (14.8%)
Regular: 0.7–1,8	15 (27.8%)	13 (24.1%)
Poor: 1.9–3.0	28 (51.8%)	33 (61.1%)
Type of cavity		
occlusal	27 (50%)	27 (50%)
occlusoproximal	27 (50%)	27 (50%)

* Oral hygiene was considered in accordance to the Greene and Vermillion index.

Table 2. Logistic regression analysis comparing pulp vitality between the groups.

Groups	Pulp vitality		OR (95%CI)
	Success	Failure	
	n (%)	n (%)	
CHC + HVGIC	38 (70)	16 (30)	Ref.
HVGIC	37 (68.5)	17 (31.5)	1.091 (0.481–2.475)

Lining deep cavities is advocated for dentin-pulp complex protection to reduce postoperative complications.[21] The remineralization of caries tissue and induction of reactionary dentin formation have been mentioned as advantages of CHC application as a liner.[21,22] However, no clinical advantage of CHC application was found in our study. The selective carious removal was probably enough to protect the dentin-pulp complex allowing the pulp tissue to repair from the carious aggression. The removal to soft dentine on the pupal floor prevents accidental pulp exposure and stress to the pulp, while maintaining a barrier that preserves pulp health.[9]

Our finding corroborates previous studies that suggest that pulp vitality can be maintained with selective caries removal and filling of the cavity with a restorative material, even though a liner had not been used.[10-13] An essential requirement to assure the caries arrest after selective caries removal is the proper sealing of the cavity margin. Therefore, the carious tissue in peripheral enamel and in the dentin-enamel junction must be completely removed, allowing an adequate marginal adhesion of the restorative material, providing an effective seal.[9]

Overall, glass ionomer cements have shown good results in deep cavity restorations and maintenance of pulp vitality.[10] Although no previous randomized clinical trial has evaluated HVGICs for filling deep cavities in primary teeth, conventional GIC has shown adequate biocompatibility characteristics,[23] which could explain our findings. Moreover, previous studies on permanent teeth using HVGIC as a dentin-pulp complex protective material before the restoration

Table 3. Distribution of success and failure rate of pulp vitality according to the type of cavity at 12 and 24 months for both groups.

Variable	12 months		p-value	24 months		p-value
	Success	Failure		Success	Failure	
	n (%)	n (%)		n (%)	n (%)	
CHC + HVGIC						
Occlusal	25 (92.6)	2 (7.4)	0.018	22 (81.5)	5 (18.5)	0.040
Occlusoproximal	18 (66.7)	9 (33.3)		15 (55.6)	12 (44.4)	
HVGIC						
Occlusal	23 (85.2)	4 (14.8)	1.0	18 (66.7)	9 (33.3)	0.085
Occlusoproximal	23 (85.2)	4 (14.8)		19 (70.4)	8 (29.6)	

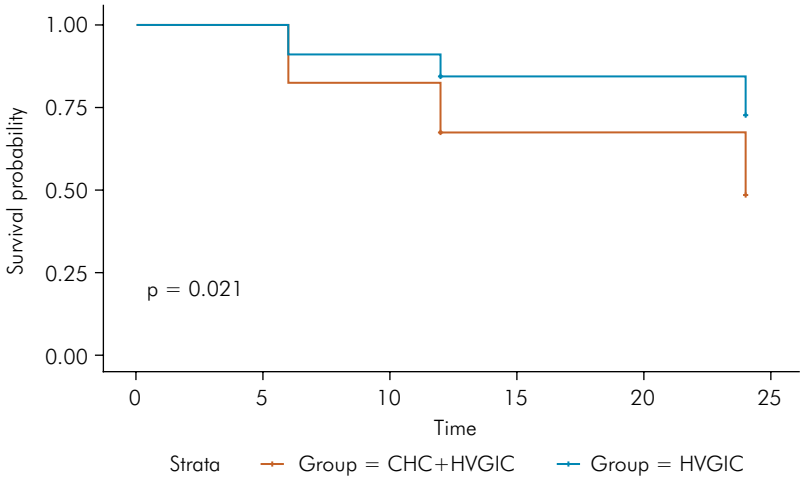

Figure 2. Kaplan-Meier curve of the survival analysis of restorative procedures.

Table 4. Cox regression analysis (Hazard Ratio; 95% Confidence Interval) for failure of restorations according to explanatory variables.

Variables	Survival	Unajusted HR	p-value
	n (%)	(95% CI)	
Restorative groups			
CHC+HVGIC	23 (50)	Ref.	0.024
HVGIC	33 (73.3)	0.45 (0.22–0.90)	
Sex			
Female	27 (62.8)	Ref.	0.779
Male	29 (60.5)	1.1 (0.56–2.14)	
Jaw			
Upper	20 (55.6)	Ref.	0.298
Lower	36 (65.5)	1.43 (0.73–2.78)	
Tooth			
First molar	30 (65.1)	Ref.	0.643
Second molar	26 (57.8)	1.2 (0.60–2.3)	
Surface			
Occlusal	28 (57.1)	Ref.	0.294
Occlusoproximal	28 (66.7.)	0.70 (0.35–1.37)	

mentioned that this presents a biocompatibility comparable with CHC, resulting in a pulp vitality of deep caries lesion treated with it.[24,25] Conversely, the better longevity expected with this material corroborates the caries arrest process.[26] The findings of this study are even more relevant when adopting the ART approach. The management of deep caries without anesthesia (when possible), rotary instruments, or rubber dam allows for a friendlier dental care,[18] resulting in lower anxiety and pain by children.[6]

It is necessary to highlight that the success of a restorative treatment for deep cavities depends on the correct diagnosis of the pulp condition, which in pediatric patients can be difficult.[27] Thus, treatment failures could be more associated with an incorrect pulp health diagnosis than with the technique itself,

being a possible limitation of studies, such as ours, that considered pulp vitality as the outcome. This fact can also explain the success rate found in our study. However, the thorough diagnosis of pulp health with association of clinical and radiographic evaluations can have minimized the risk of inaccurate diagnosis. Similar characteristics has considered as criteria for success in a previous study focusing on pulp vitality of primary teeth.[17] Moreover, the teeth included in this study did not have any sign of pulp necrosis, irreversible pulpitis, or chronic degenerative changes that would require another type of pulp treatment, such as endodontic treatment.

On the other hand, the HVGIC group showed a higher success rate than the group that received also CHC protection. A lower annual failure rate for restorations with HVGIC alone was observed. The presence of an extra interface with CHC before HVGIC can result in a higher chance of failure, besides reducing the area of the tooth surface available for adhesion. A previous study suggested that the application of CHC can jeopardize the restoration in terms of margin integrity and fracture resistance.[21] Furthermore, the solubility of CHC in contact with fluid from dentinal tubules has been broadly discussed, which can result in restoration displacement and marginal leakage over time.[21,22,28] Because deciduous molars are small teeth, placing two layers of materials (lining and filling) in a cavity could be challenging and represents an additional and unnecessary step in the treatment; thus, a simpler technique would be advantageous. In this context, it has been expected that the survival rate of occlusal and occlusoproximal restorations could be different between them. Thus, the inclusion of both occlusal and occlusoproximal cavities could be considered as a limitation of our study. However, we performed the randomization stratified according to the type of cavity, which showed no influence on the survival rate of ART restoration.

In this panorama, the results from this randomized clinical trial support that the layer of CHC in the base of deep cavities before filling with glass ionomer cement does not provide clinical advantages concerning restoration longevity and pulp vitality. HVGIC restorations following the ART approach are recommended for deep caries in primary teeth. Evidence-based dentistry encourages the inclusion of the patients' needs and preferences during the decision-making process of carious lesions management. Thus, the conduction of well-designed studies focusing on this topic should be performed.

Conclusion

Deep caries lesions in primary molars treated with high-viscosity glass ionomer cement in ART approach results in similar pulp vitality of the application of hydroxide calcium cement as liner associated with high-viscosity glass ionomer cement, but with a higher survival rate of restoration.

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