RESEARCH ARTICLE

New Dual-cure Resin-based Material in Occlusal and Occluso-proximal Restorations of Primary Teeth: Results of a Randomized Clinical Trial

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Abstract

Background: The clinical performance of new restorative materials must be evaluated before recommending its use in primary teeth.

Aim: This randomized clinical trial evaluated the survival rates of restorations in single and occluso-proximal cavities of primary teeth performed with a new dual-cure resin-based material in comparison with a resin-modified glass ionomer cement after 12 months of follow-up.

Materials and methods: A total of 107 restorations were placed in 27 children by one experienced pediatric dentist. Two materials were tested: Vitremer and a dual-cure resin-based material with (CentionN+Adh) and without (Cention N–Adh) adhesive system application. Two calibrated and blinded examiners evaluated the restorations at 3, 6, and 12-month. The longevity of the restorations was analyzed using Kaplan-Meier survival curves and Log-rank test (α = 5%).

Results: The overall survival rates after 12-month were 81.9% for Vitremer, 70.4% for Cention N+Adh, and 66.7% for Cention N–Adh, which had the poorer performance (HR = 0.54; 95% CI= 0.31–0.95; $p = 0.031$). When considering the type of the cavities, the difference was significant only for occluso-proximal cavities when Cention N–Adh was used (HR = 0.46; CI = 0.26–0.81; $p = 0.008$).

Conclusion: All evaluated materials are suitable for restoring occlusal cavities after selective caries removal. However, Cention N needs to be used with adhesive in occluso-proximal cavities.

Clinical significance: Cention-N can be used for deciduous teeth restorations, with similar longevity rates as resin modified glass ionomer cements.

Trial registration number RBR-9nqszr

Keywords: Deciduous, Dental atraumatic restorative treatment, Glass ionomer cements, Survival rate, Tooth.

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Introduction

When restoring a carious lesion, dentists should aim the inactivation/control of the disease process, preservation of dental hard tissues, avoidance of initiating the cycle of restoration, and the maintenance of the tooth as long as possible.[1] These principles were defined at the International Caries Consensus Collaboration meeting in 2015, and they are based on a biological and minimally invasive approach for dental restorations. Therefore, when a restoration is needed, the preparation of the tooth should focus on selective removal of the carious dentin; and the restoration on the protection of pulp-dentine complex and good cavity seal.[1,2]

In agreement with these up-to-date concepts, one of the best choices of restorative treatment for deciduous teeth is the selective removal of carious dentin followed by an adhesive restoration of the cavity, as preconized by the Atraumatic Restorative Treatment protocol (ART), that comprises the removal of soft, completely demineralized carious tooth tissue, using hand instruments, followed by the restoration of the cavity with a high-viscosity glass ionomer cement (HVGIC).[3] This approach also represents a patient-friendly restorative procedure[4] and it was shown similar longevity rates when compared to "conventional" restoration procedures in deciduous teeth.[5-8]

The longevity rates for multiple surfaces restorations is still lower than single surface ones, and this finding may be related to the fact that HVGICs show some features that still need improvement. Glass ionomer cement (GIC) suffers from longer setting times, so the maximal mechanical properties of this material are not achieved immediately after the placement of the restoration. Besides, GICs can be difficult to handle, leading to cervical gaps due to inadequate adaptation to the cavity walls.[9]

Alternative materials have been launched trying to overcome the problems of GIC. Recently a new category of filling material, Cention N, classified as a subgroup of the composite material class (alkasite composites) was launched. It was developed as an alternative to GICs and amalgam.[10] It is a power-liquid dual-cure resin-based material that which, after manipulation, exhibits a paste-like consistency, facilitating the insertion into the cavities, and allowing its use as a bulk material.[11] According to the

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manufacturer's descriptions, Cention N contains alkaline fillers that release hydroxide, fluoride, and calcium ions to regulate the pH value during acid attacks.[11]Due to the higher amount of filler, this product has shown higher mechanical properties than GIC.[12,13]

This new material has been recently evaluated in permanent teeth as conventional restorative material.[14] However, to the best of our knowledge, the clinical performance of Cention N restorations with selective caries removal in primary teeth has not been reported in the literature yet. Thus, this clinical study aimed to compare the survival rate of occlusal and occluso-proximal restorations after selective caries removal in primary teeth, performed with Cention N associated or not to an adhesive system and a resin-modified GIC after 12 months of clinical service. The null hypothesis tested was that no difference would be detected in the survival rates of restorations performed with the different materials tested in the 12-month follow-up period.

Materials and Methods

This article has been prepared according to the protocol established by the Consolidated Standards of Reporting Trials statement–CONSORT.[15]

Ethical Approval

The local Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and issued a consent form for this study (protocol 2.064.952). Written consents were obtained from parents/guardians of the participating patients.

Protocol Registration

This clinical trial was registered in REBEC (www.ensaiosclinicos.gov.br)clinical registry under protocol number U1111-1198-3193. All participants were informed about the nature and objectives of the study.

Trial Design, Settings and Locations of Data Collection

This was a double-blind, superiority, split-mouth randomized clinical trial with an equal allocation ratio. All procedures in the selected volunteers were performed from August 2017 to December 2017.

Recruitment

The children included in the clinical trial were evaluated in municipal schools in the local city and, therefore, the child was chosen by convenience sampling (according to eligibility criteria). No type of advertisement was done in any type of media.

Eligibility Criteria

To be included in the trial, participants should be between 4 and 9 years old, without systemic diseases. They should present at least three primary posterior teeth with carious lesions in vital teeth. Cavities should be scored 5 or 6 in the ICDAS system,[16] since open access to carious dentin should be present. All cavity preparations were done by hand instruments, according to the ART guidelines.[17]

Participants were excluded if abscess, fistula, or spontaneous pain were present. Children who did not accept the clinical exam, nor attended the scheduled day for restoration and those whose parents/guardians did not sign the Informed Consent Form were excluded.In such circumstances, parents were advised to seek dental care in the National Health System.

Sample Size Calculation

The failure rate of Vitremer restorations in the item fracture/retention/carious lesion adjacent to the restoration was was reported to be approximately 55%.[18] Thus, a minimum sample size of 33 restorations per group was required to have an 80% chance of detectingan increase in the primary outcome measure from 55% in the control group (Vitremer, 3M Oral Care, St. Paul, MN, USA) to 85% in the experimental group (Cention N, IvoclarVivadent, Schaan, Liechenstein), with a 5% significance level.

Random Sequence Generation and Allocation Concealment

The randomization was done on an intra-individual basis so that each subject ended up with three restorations, each one resulting from one of all possible restorative procedures. We used blocked randomization (block size of 3) with an equal allocation ratio to form the allocation list for the three comparison groups. These randomization schemes were performed using the tools available at http://www.sealedenvelope.com (Clerkenwell Workshops, London EC1R 0AT, UK).

A staff member who was not involved in the research protocol performed the randomization process with computer-generated tables. Details of the allocated groups were kept on cards inside sequentially numbered, opaque, sealed envelopes. Each envelope was opened only on the day of the restorative procedure with the patient in the dental chair, which guaranteed the concealment of the random sequence. In all cases, the tooth with the highest tooth number received the first treatment, while the teeth with the next numbers in the sequence received the second and third treatments listed. The restorations were always placed in different sextants in the same patient.

Study Intervention

Two different materials were tested: Vitremer (3M Oral Care, St. Paul, MN, USA) and Cention N (IvoclarVivadent,Schaan, Liechtenstein). The materials specifications are summarized in Table 1. Cention N was tested using two different protocols: without adhesive(Cention N-Adh) and with adhesive application (CentionN+Adh)before restoration with Cention N.

All restorations were carried out at school environment, in a classroom adapted for this purpose, by one experienced pediatric dentist assisted by a dental student.

The restorations were done without local anesthesia and the operatory field was isolated with cotton rolls. The cavity preparation followed the sequence described below: (1) tooth surface was cleaned with a wet cotton pellet to remove debris and dental biofilm; (2) the infected dentin was removed from the surrounding walls, cavo surface margin and the enamel-dentin junction using sharp dentin excavators (Kit ART 10 Instruments Set, GC Europe, Leuven, Belgium) of appropriate size. In order to avoid pulpal exposure, the carious dentin on the pulpal floor was left untouched. The cavity was then cleaned with a small cotton pellet soaked in water and dried with a dry cotton pellet (Cremer, Blumenau, SC, Brazil). No cavity liner was used. For occluso-proximal restorations, after the cavity preparation, a metallic matrix (TDV, Pomerode, SC, Brazil) was adapted to define the proximal contour of the restoration.

Table 1: Restorative materials: composition and application mode

Restorative materials (batch number)	Composition (*)	*Application mode (*)*		
		Adhesive/Primer application mode		*Restorative material*
Vitremer (3M Oral Care)	1. Vitremer primer: Vitrebond copolymer, 2-hydroxyethyl methacrylate, ethanol and photoinitiators. 2. Vitremer Powder: fluoroaluminosilicate glass and redox system 3. Vitremer Liquid: aqueous solution of a modified polyalkenoic acid, 2-hydroxyethyl methacrylate, and photoinitiators	Yes (**Vitremer**)	1. Apply primer to enamel and dentin and scrub for 30 seconds 2. Gently air dry for 10 seconds 3. Light-cure for 20 seconds at 1200 mW/cm^2	1. Dispense 1 scoop of powder and 1 drop of liquid next to each other on a mixing pad plate. 2. Mix the powder and the liquid for 45 seconds). 3. Apply the material to the cavity, condense it thoroughly and then sculpt the occlusal anatomy. 4. Light-cure for 10 seconds at 1200 mW/cm^2
Tetric N-bond Universal (S 54,248) and Cention N (Ivoclar Vivadent, Schaan, Liechnstein)	1. Tetric N-bond Universal: 2-hydroxyethyl methacrylate, methacryloyloxydecyl dihydrogen phosphate, bisphenol glycidyl methacrylate, methacrylated carboxylic acid polymer, decandiol dimethadrylate, ethanol, water, highly dispersed silicon dioxide, and camphorquinone 2. Cention N Liquid: 4 Urethane dimethacrylate, Tricyclo-decan-dimethanol dimethacrylate, Tetramethyl-xylylen-diurethane dimethacrylate, and Polyethylene glycol 400 dimethacrylate and initiators. 3. Cention N Powder: Barium aluminium silicate glass filler, ytterbium trifluoride, an Isofiller, a calcium barium aluminium fluorosilicate glass filler, and a calcium fluorosilicate (alkaline) glass filler, with a particle size of between 0.1 µm and 35 µm, initiators and pigments	No (**Cention N - Adh**)	-	1. Dispense 1 scoop of powder and 1 drop of liquid next to each other on a mixing pad plate. 2. Mix the powder and the liquid on the mixing pad using a plastic spatula until a homogeneous, creamy consistency is achieved (45–60 seconds). 3. Apply the material to the cavity, condense it thoroughly and then sculpt the occlusal anatomy. 4. Light-cure for 10 seconds at 1200 mW/cm^2
		Yes (**Cention N - Adh**)	1. Scrub one coat of adhesive for 20 seconds 2. Gently air thin for 5 seconds 3. Light-cure for 10 seconds at 1200 mW/cm^2	

(*) According to the manufacturer's instructions

For the Vitremer restorations, the primer of the material was applied before restoration and light-cured for 20 seconds with a LED device (Bluephase N, IvoclarVivadent, Schaan, Liechtenstein), intensity of 1.200 mW/cm^2. The material was manipulated by one trained operator, inserted into the cavity, the excess of the material was removed and it was light-cured for 40 seconds with the same LED device. Vitremer was mixed and applied following the manufacturer's instructions, however, no finishing gloss was applied to the surface of the material.

For the CentionN restorations with adhesive (CentionN+Adh), one coat of the adhesive Tetric N-Bond Universal in the self-etch mode (IvoclarVivadent, Schaan, Liechtenstein) was applied actively, scrubbing during 20 seconds in the enamel and dentin. After this time, a gently air jet was applied for 5 seconds and it was light-cured for 10 seconds (1.200 mW/cm^2; Bluephase N, IvoclarVivadent). Cention Npowder and liquid were handled mixed according to the manufacturer's instructions and inserted into the cavity in bulk. After the removal of the material excess, restorations were light-cured for 40 seconds (1.200 mW/cm^2; Bluephase N, IvoclarVivadent).

Cention N restorations without adhesive (Cention N-Adh), followed the same protocol previously described, without the application of the adhesive.

Blinding

The examiners that performed the clinical evaluation were not involved with the restoration placement procedures and were blinded to the group assignment. Patients were also blinded to group assignment in a double-blind randomized clinical trial design. This was possible because, after restoration placement, the materials presented a similar clinical appearance.

Clinical Evaluation

Two calibrated and blinded examiners evaluated the restorations at 3, 6, and 12 months. Debris and plaque from the tooth surface were removed before evaluation using a wet cotton pellet.

Clinical evaluation was performed at school environment, using WHO periodontal probes, plane front-surface mirrors and a light source. The ball of the CPI probe (diameter 0.5 mm) was used to measure the size of any marginal gap and the amount of wear. The evaluation criterion to evaluate the restorations was those of a previous study.[19] Restorations scored as codes 0, 1, and 2 were considered successful, those scored as codes 3, 4, 5, 6, 7, and 8 were considered failures, and the restorations scored code 9 (unable diagnostic)were replaced with the last score obtained in the previous evaluation. Both examiners evaluated all the restorations once and independently. An intra and inter-examiner kappa test was performed during the clinical evaluations. However, in the case of disagreements during evaluations, they had to reach a consensus before the participant was dismissed.

Statistical Analysis

The statistical analyses followed the intention-to-treat protocol according to the CONSORT statement .[15] Inter-examiner agreement was assessed with kappa coefficient values. Descriptive statistics included the success rate of the restorative materials at both 3, 6, and 12 months.

In order to evaluate the intensity of the association among the success rates of the different restorative materials used, hazard ratio (HR) was calculated, considering an overall analysis and different types of restorations (occlusal and occluso-proximal); a 95% confidence interval was stipulated.

Kaplan-Meier survival curves were obtained considering different materials, types of restorations and overall curve. Log-Rank (Mantel-Cox) test was used to analyze the differences between survival curves: (1) for different materials, (2) for different types of restoration, (3) for different materials in the same type of restoration, and (4) for different types of restoration using the same material. It was applied in uncensored and censored data (restorations scored as code 9). A difference was considered statistically significant if $p < 0.05$. All analysis were carried out using IBM SPSS Statistics for Windows, Version 20.0 (Armonk, NY: IBM Corp).

Results

The experimental protocols were implemented exactly as planned, and no modifications were performed. A total of 433 children were examined and 27 children with a mean age of 6 + 2 years old (range from 4–9) constituted the study sample (Table 2). Reasons for exclusion can be seen in Flow chart 1. One-hundred and seven restorations were placed (Vitremer n = 35; Cention N + Adhn = 36; Cention N–Adhn = 36) (Table 2).

The number of successful and failure restorations according to each score is depicted on Table 3. A higher number of failures occurred in the occluso-proximal cavities when compared with occlusal cavities in all periods of evaluation. For the occlusal restorations, it can be seen that neither Vitremer nor Cention N +Adh restorations presented failures at 3 months and 6 months (Table 3).

Survival curves, with censored and uncensored data, are presented in Figures 1, 2 and 3. Log-rank Mantel-Cox test did not indicate a difference among materials in overall analysis ($p = 0.052$) (Fig. 1) or when occlusal restorations were considered (Fig. 2) ($p = 0.3150$). Notwithstanding, significant differences were detected between restorative materials in occluso-proximal restorations ($p = 0.005$) (Fig. 3). There was no difference between censored and uncensored data.

Hazard ratio (HR) was calculated using Vitremer as reference material as we investigated the intensity of the association between restorative material and the success of the restorations (Table 4). In an overall analysis, Cention N–Adh had poorer performance among all the tested materials (HR = 0.54; CI= 0.31–0.95; $p = 0.031$). When considering the type of the cavities, difference was significant

Table 2: Characteristics of the children and features of the restored cavities for both study groups

Characteristics of research subjects	*Number of children*		
Gender distribution			
Male	17		
Female	10		
Age distribution (years)			
4 to 6	13		
7 to 9	14		
Number of lesions (n=108)			
Cention N - Adh	Vitremer	Cention N + Adh	Type of cavity
Occlusal	06	13	6
Occlusal-proximal	29	23	30
Tooth distribution			
First primary molar	13	13	18
Second primary molar	22	23	18
Arch distribution			
Maxillary	16	20	13
Mandibular	19	16	23

Table 3: Scores of failure plus score 9 (unable to diagnose) according to the restorations size and evaluation period for each treatment at 3, 6 and 12 months of clinical evaluation

Period	*Treatment*	*3*	*6*	*7*	*8*	*9*	*3*	*6*	*7*	*8*	*9*
3-month	Vitremer	-	-	-	-	01	02	02	-	-	06
	Cention N-Adh	-	-	-	-	01	01	04	02	01	02
	Cention N+Adh	-	01	-	-	01	-	05	-	01	05
6-month	Vitremer	-	-	-	-	01	01	04	-	01	07
	Cention N-Adh	-	-	-	-	01	-	06	03	02	05
	Cention N+Adh	-	01	-	-	03	03	05	-	01	03
12-month	Vitremer	-	01	-	-	01	02	05	-	01	04
	Cention N-Adh	-	-	-	01	03	-	11	03	02	02
	Cention N+Adh	-	03	-	-	02	01	09	-	02	01

(*) Only scores 3, 6–9 were observed along of this clinical evaluation

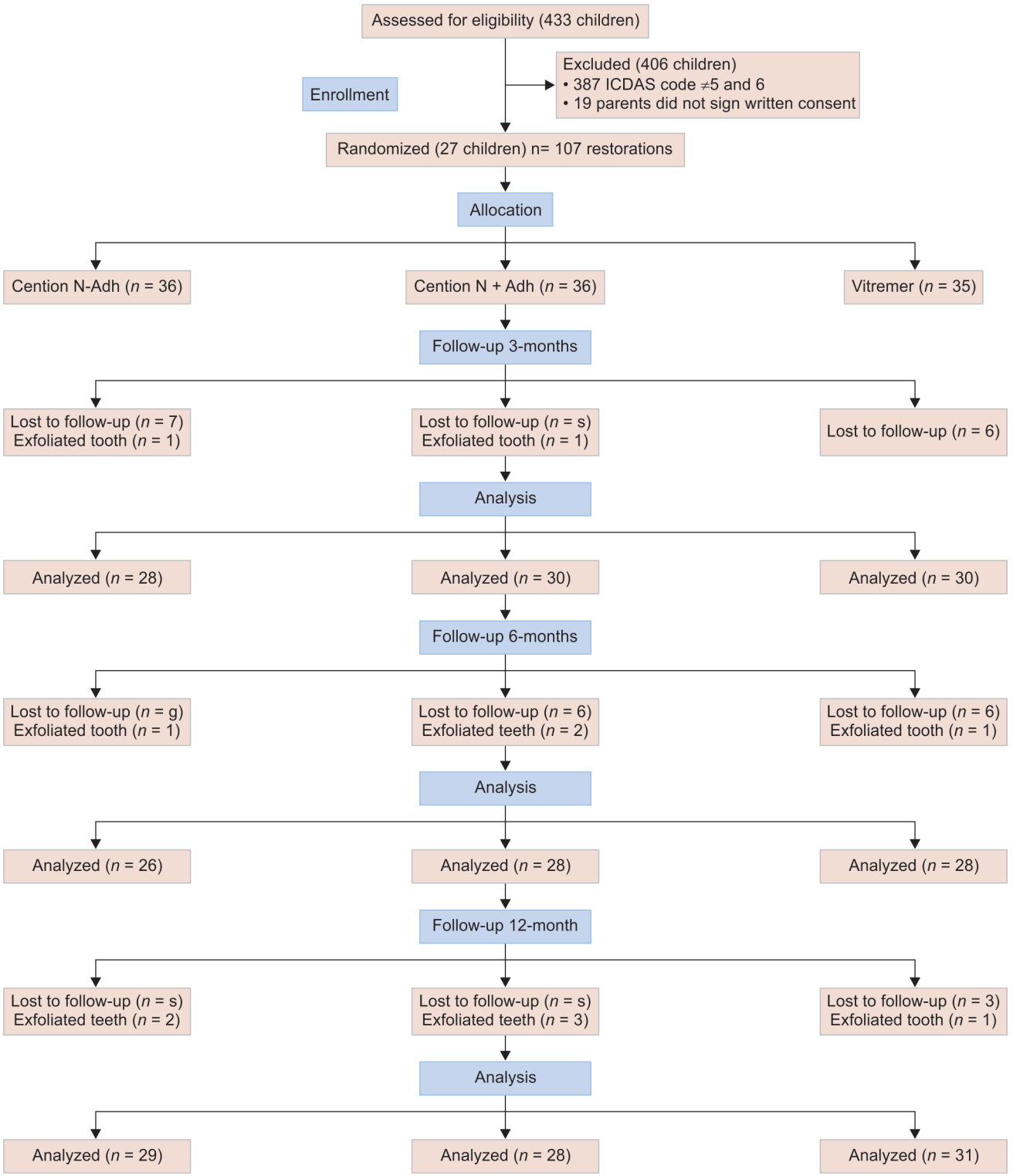
only for occluso-proximal cavities when Cention N–Adh was used (HR = 0.46; CI = 0.26–0.81; $p = 0.008$).

No differences were detected for the risk of success when Vitremer was used as a restorative material for occlusal or occluso-proximal restorations (HR = 3.72; CI = 0.49–27.89; $p = 0.201$). However, the chance of success increased 3.05 (CI 95%=1.17–7.93; $p = 0.022$) and 13.46(CI 95%=1.84–98.26; $p = 0.010$) times in occlusal restorations for Cention N–Adh and Cention N + Adh, respectively when compared to occluso-proximal restoration.

Discussion

The clinical performance of new restorative materials must be evaluated, since they may present a solution for the low longevity

Flowchart 1: Study participants



rates of multiple surface restorations in primary teeth (Olegário et al.; De Amorim et al.), which is a real challenge for pediatric dentist's clinical practice.

In an overall analysis of the restorations, irrespective of the number of surfaces involved, our results showed that restorations in primary teeth using the resin-based restorative material showed similar longevity rates as the restorations made with the commonly used resin-modified GIC. Notwithstanding, literature shows that there is a remarkable difference between longevity rates of occlusal and occluso-proximal cavities[20,21] which instigate the authors to perform additional statistical analysis based on this criterion. Indeed, this allowed us to observe that survival rates of occlusal restorations were not influenced by the restorative material, whereas occluso-proximal restorations exhibited poorer performances, particularly when Cention N was used without adhesive system. Therefore, the use of an adhesive system is strongly recommended, mainly when Cention N is used for restoring occluso-proximal cavities.

The strategy behind this clinical trial was to associate several positive aspects of the ART (no need of local anesthesia, absolute isolation and rotatory instruments, and possibility of treatment outside of the dental office) to the use of light-cured/bulk restorative materials,that allows better time management for the dentist during the restorative procedure.The restorations were performed in a minimally invasive approach by selective carious removal in deep cavities. Therefore, this is probably one of the best way for treating pediatric patients nowadays, that takes into account the biological management of carious lesions[1] and contributes to the behavior management of the children.

It is expected that materials with a resin component (like compomers and resin-modified glass-ionomers) have similar survival rates in primary teeth.[22] Therefore, in the present study, it was selected the most used resin-modified GIC in randomized clinical trials of deciduous teeth restorations (Vitremer- 3M Oral Care, St Paul, MN, USA)[23] as the control group material.

Literature had already shown the lack of superiority between the most commonly used restorative materials in Pediatric Dentistry when complete caries removal protocol was used (compomer, resin-modified glass-ionomer, amalgam, and composite resin).[23] This is also true for restorations with selective carious tissue removal, as in the ART protocol, that showed similar longevity rates when comparing HVGIC ART restorations to conventional restorations with different restorative materials.[5,19] This way, the development of a new restorative material demands implementation of randomized clinical trials to establish the real possibilities of Cention N clinical usage in this scenario.

Although the manufacturers stated that Cention N can be used in deciduous teeth, to the authors' knowledge, currently there are no published papers which have addressed its use in deciduous teeth[10] and primary affected dentin. It is also stated that Cention N can be used with or without adhesive system, so we decided to investigate both protocols.

When Cention N is used without adhesive system, it is explicitly described in the Cention N recommendations that "retentive preparation should be ensured."[10] However, we followed the concepts of minimal intervention and no extra retention was performed, since additional lost of sound dental tissue is currently not acceptable.

It is recognized that when the resultant preparation is shallow with divergent walls, retention in composite resin restorations is largely determined by the ability of adhesives to bond to the cavity walls.[24] Probably, this fact contributed to the lower success

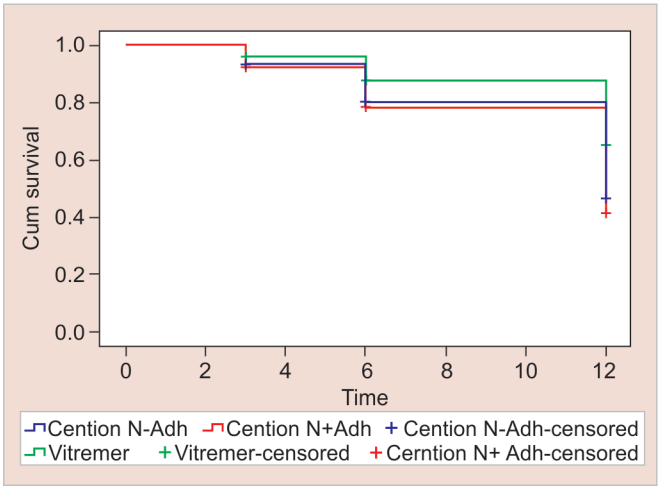


Fig. 1: Kaplan-Meier survival estimates among the materials for restorations in primary teeth (log-rank p = 0.052)

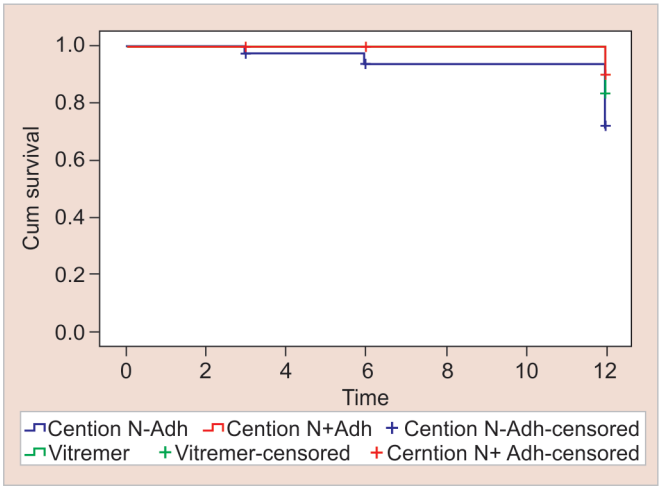


Fig. 2: Kaplan-Meier survival estimates among the materials for occlusal restorations in primary teeth (log-rank p = 0.315)

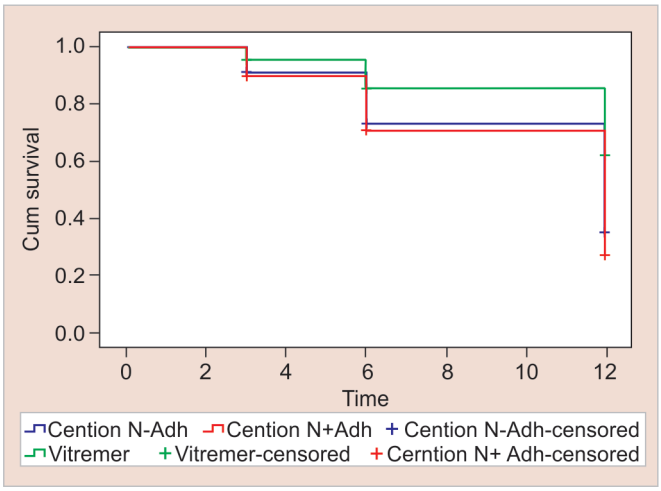


Fig. 3: Kaplan-Meier survival estimates among the materials for occlusal-proximal restorations in primary teeth (log-rank p = 0.005)

Table 4: Cox regression analysis of success in occlusal and occluso-proximal restorations associated with restorative materials tested

		Success		HR	
Variable	*Comparison*	*N*	*%*	*(IC 95%)*	*p-value*
Overall comparison	Vitremer	86	81.9	Reference	
	Cention N - Adh	72	66.7	0.89 (0.55–1.43)	0.628
	Cention N + Adh	76	70.4	0.54 (0.31–0.95)	0.031
Occlusal	Vitremer	17	94.4	Reference	
	Cention N - Adh	29	96.7	3.85 (0.45–32.92)	0.219
	Cention N - Adh	34	87.2	1.67 (0.10–26,65)	0.718
Occluso-proximal	Vitremer	69	79.3	Reference	
	Cention N - Adh	43	55.1	0.87 (0.53–1.44)	0.593
	Cention N + Adh	42	60.9	0.46 (0.26–0.81)	0.008
Vitremer	Occlusal	17	94.4	3.72 (0.49–27.89)	0.201
	Occluso-proximal	69	79.3		
Cention N + Adh	Occlusal	34	87.2	3.05 (1.17–7.93)	0.022
	Occluso-proximal	42	60.9		
Cention N - Adh	Occlusal	29	96.7	13.46 (1.84–98.26)	0.010
	Occluso-proximal	43	55.1		

rates of Cention N–Adh in the present study, which occurred even in occlusal cavities (3 restorations were lost after 12 months of follow-up).

Therefore, to ensure improved adhesion, Cention N must be associated with an universal adhesive, that can be used in a one-step self-etch technique or associated with phosphoric acid etching.[25,26] Since there is no difference among techniques[27] and simplification of the bonding procedure is a clinical goal in Pediatric Dentistry, universal adhesive was applied in the self-etch mode. It was already showed that universal adhesives in one step model perform equally as etch-and-rinse strategy in primary teeth after partial caries removal, with good survival rates of composite resin restorations after 12 months of follow-up.[28] As for the resin-modified GIC, the use of a primer previously to the final restoration forms a submicrohibrid layer that is similar to the one produced with self-etch adhesives[29] and may contribute to the longevity of the adhesive interface[30] and consequently, the survival rate of the restorations.

Even so, there were failures, especially in occluso-proximal restorations, even when Vitremer and Cention N + Adh were considered. Several factors could be responsible for this issue. Bonding to caries-affected dentin is a clinical challenge, mainly because of several chemical, biological and physical modifications,[31,32] resulting in lower bond strength when compared to sound dentin,[33] due to a poorly hybridized hybrid layer.[34] The same phenomenon occured when Vitremer was applied to caries-affected dentin.[30]

Another problem is the possibility of saliva contamination. It is known that saliva contamination jeopardizes the resin-dentin bonding strength to self-etch adhesive.[35,36] Both rubber dam and cotton rolls are currently used in dentistry. A closer view regarding the influence on saliva contamination in the survival rate of the restorations shows conflicting results. Regarding survival rates of occlusal-proximal ART restorations after 2 years, there are results showing no difference between cotton wool rolls or rubber dam isolation[37] and better rates with rubber dam use.[38] A recent systematic review about survival rates of conventional restorations in primary teeth pointed out that restorations placed using rubber dam presented better survival rates.[39] Therefore, it is clear that future clinical trials should be done in order to investigate the performance of Cention N when restorations are placed under rubber dam isolation.

However, the most important factor is that the majority of the failures were concentrated in occlusal-proximal cavities and the main cause of failure, regardless of the study group, was the loss of the restoration. Multi-surface fillings have been identified as risk factors for failures in deciduous teeth restored with total[39] or partial caries removal in the ART approach.[40-42]

It would be expected that Cention N could overcome this flaw since the manufacturer states that it presents higher mechanical properties compared to conventional (Fuji II) and different HVGICs brands.[10] Also, we opted to use Cention N in dual-cure mode, as light-curing the material resulted in higher Vickers hardness.[10]

However, these expectations were not fulfilled and, to a certain point, patient-related reasons may be responsible for this. Although patients enrolled in this study received oral hygiene instructions at the beginning of the trial and again at each follow-up appointment, we selected patients with at least three carious cavities in posterior teeth (ICDAS 5 and 6), which is indicative of an active caries profile. Literature shows that a high level of caries prevalence may influence the posterior restoration survival in primary teeth[43,44] and permanent teeth[45] of children. Therefore, this could have influenced our results, as the presence of a cariogenic biofilm, that acts both on tooth and restorative material surfaces, may impair restorations' survival.[44]

The fluoride release exhibited by both restorative materials could help to control this situation. Vitremer[46] and Cention N can be recharged by a topical fluoride application and Cention N has the same fluoride release pattern as Vitremer.[47] Cention N contains alkaline fillers that release hydroxide, fluoride and calcium ions to regulate the pH value during acid attacks[11] and according to the manufacturer's descriptions, these ions will be able to prevent tooth demineralization.[10] Unfortunately, this was not measured in the present clinical trial and future studies are

needed to evaluate the effect of Cention N in preventing new caries lesions around restorations.

It is worth mentioning that, during this 12-month follow-up period, we did not detect any pulp pathology, pain, facial swelling, or sinus tract, which confirms the success of selective caries removal in primary teeth as stated by the dental literature[48,49] and the absence of negative pulp reactions to all restorative materials evaluated.

Conclusion

All evaluated materials are suitable for restoring occlusal cavities after selective caries removal. However, Cention N needs to be used with adhesive in occluso-proximal cavities, due to poorer performance of the Cention N without adhesive after 12 months of follow-up.

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