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Clinical Performance of Cention^{TM} Alkasite Restorative Material vs. Glass Ionomer Cement Used in Deciduous Teeth: One-Year Evaluation

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Abstract: Conservative dentistry in primary dentition aims to remove and repair existing carious lesions and to prevent secondary caries up until exfoliation of the primary tooth happens, in order to maintain the important role in terms of the space maintenance and guidance for eruption that deciduous teeth have. Many different materials are used, and some of them, recently commercialized, show bioactive properties able to prevent secondary caries. This trial's primary focus is to evaluate the biological, functional, and aesthetic characteristics of Cention-N alkasite material compared to glass ionomer cement (GIC) through the use of standardized FDI criteria for direct restorations. A blinded, split-mouth study was designed for this purpose, including 112 deciduous molars in 45 children showing class II caries restored with either GIC or alkasite material. The data from this study indicates that the Cention-N alkasite material showed equal performance compared with Fuji IX GIC after one year. A thorough evaluation of exfoliated teeth restored with this material will provide long-term data and an evaluation on infiltration rates.

Keywords: primary dentition; caries; glass ionomer cement; alkasite material; Cention

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1. Introduction

Caries in primary dentition have a prevalence of up to 90% worldwide [1]; in Italy, prevalence varies from about 43% at age 12 to 21% at age 4 [2,3].

Many different factors influence the results of a restorative treatment: patient's compliance, adherence to post-treatment recall programs, state of dentition development, assessment of caries risk and, most importantly, which material is chosen for the restoration [4]. This last factor may be directly influenced by the patient's compliance, because a scarce compliance often makes it difficult (if not impossible) to isolate and access the lesion properly.

For restoring posterior primary teeth, the available restorative materials include glass ionomer cement (GIC), resin modified glass ionomer cement (RMGIC), high-viscosity glass ionomer cement (HVGIC), amalgam (AM), composite resin (CR), pre-made steel crowns (SSC), and compomer (CP) [4]. Some of these materials are also used for cementation of orthodontic brackets [5].

There is both a lack of agreement and of scientific evidence in dental literature regarding which restorative material is the best choice to restore caries in primary dentition [6,7]. The choice between the different materials available for restoring primary is influenced by different aspects, including repeatability of the used technique, substrate characteristics, cavity design, and aesthetic requirements [8].

Glass ionomer cements (GICs) are provided in a base/catalyst formulation, with a basic powder and an acid liquid that need to be mixed. The base powder composition is based on three components: silica (SiO_2), aluminum oxide (Al_2O_3) and fluorite (CaF_2). The liquid component is usually a mixture of organic acids [9,10].

This material is self-curing, thanks to a reaction between the liquid polymer acids and the basic particles (acid-base reaction).

The first phase of hardening is completed after about 4 min and continues in the following hours up to 10 days after the first phase [11].

GICs adhere to tooth structure thanks to chemical and micromechanical adhesion. The first of these is provided by the formation of ionic bonds between polialchenoic acid and calcium, and the second is provided by the hybridization between the material and the collagen fibers on the surface.

Because there is no need to use etchants and adhesives, and the material is self-curing, it becomes clear that there is an high potential in using GICs in less compliant and younger patients where proper isolation is impossible and working in a quick and precise manner is essential [12].

A key property of the material is the capability of releasing fluoride ions in the surrounding tissues and saliva; they are also able to be "recharged" with the application of topical fluoride [13,14].

Thanks to this property, GICs can make the dentin and enamel surrounding the restoration more resistant to acid attacks, thereby preventing secondary caries and caries progression [15–18].

In spite of the positive aspects of this material, such as the ease of application, quick hardening, and biological active proprieties, there are some drawbacks to glass ionomer cement (GIC) that need to be highlighted. The material is inherently fragile and scarcely resistant to wear, thus making it a material ideal for provisional restorations or restoration of deciduous teeth.

Alkasite materials are a subgroup of dual cure resinous materials, usable in greater increments compared to conventional composites.

They are available in a base/catalyst formulation. The base (powder) contains glass fillers, pigments, and polymerization initiators, whereas the catalyst (liquid) contains metacrylates and polymerization initiators.

In particular, the methacrylates contained in the liquid component are as follows.

- Urethane dimethacrylate (UDMA): main component, provides the basic mechanical properties of the material.
- Tricyclodecandimethanol dimethacrylate (DCP): allows for the handling of the material and mixing of the two components and improves the mechanical properties of the material.
- Tetramethyl-xylylen-diurethane dimethacrylate (aromatic-alifatic UDMA): diminishes the colour variation of the material over time and increases elasticity.
- Polyethylene glycol 400 dimethacrylate (PEG-400 DMA) is a liquid monomer that increases the fluidity of the material and bagnability of the surface on dentin and enamel.

The fillers contained in the powder component, which are about 78.4% of the material's volume are as follows.

- Alluminosilicate (Al_2SiO_5) and barium (Ba): increases the strength of the material.
- Ytterbium trifluoride (YbF_3): provides radiopacity.
- Isofiller: made of pre-polymerized UDMA fragments, it diminishes polymerization shrinkage.
- Calcium, barium, and aluminium fluorosilicate glasses: they increase strength while providing fluoride release.
- Calcium fluoro silicate glass: releases basic ions (F^-, Ca^{2+}, OH^-) and represents the 24.6% of volume of the material.

In order to adhere to the prepared cavity, no etching is needed, while the use of an adhesive is suggested in case of non-retentive design of the cavity.

This material has the capability of releasing basic ions when saliva reaches acidic pH levels (i.e., during and after meals), preventing demineralization of tooth tissue and countering the acidic attacks by bacteria. This effect is similar to that typical of bioactive composite resins [19].

Fluoride ions are incorporated in the enamel's crystalline reticle in the form of fluorapatite, which is considerably more resistant to acid attacks compared to conventional enamel apatite.

Fluoride also has antibacterial activity, inhibiting acidic production by bacteria such as *Streptococcus mutans*, thus slowing down plaque activity and growth.

For this trial, the materials chosen were an alkasite restorative material (Cention-N, Ivoclar Vivadent AG, Schaan, Liechtenstein) and a glass ionomer cement (Fuji-IX, GC Europe, Leuven, Belgium). The use of GIC for Class I carious lesions has been suggested, whereas its use for Class II carious lesions is discussed in the literature and supported by expert opinions [20,21]. The clinical performance of the alkasite restorative material has been evaluated through the FDI parameters in a 2016 trial, suggesting its use to restore primary teeth and reporting better performance compared to GIC [22,23].

To evaluate dental restorations, the FDI criteria present three levels of evaluation [24]: aesthetic, biological and functional. Each level is comprised of 16 evaluation criteria divided in sub-groups.

- Evaluation of aesthetic properties:
  - Surface luster;
  - Surface staining;
  - Color stability and translucency; and
  - Anatomic form.
- Evaluation of biological properties:
  - Post-operative sensitivity and tooth vitality;
  - Secondary caries;
  - Tooth integrity and enamel cracks;
  - Periodontal response compared to a reference tooth;
  - State of the mucosa adjacent to the restoration; and
  - Oral and general health.
- Evaluation of functional properties:
  - Retention and fracture of the restoration;
  - Marginal adaptation;
  - Wear of the restoration;
  - Presence and persistence of the contact point;
  - Presence of food impaction;
  - Radiographic examination (if available); and
  - Patient's view (opinion of the patient or, in this case, of the parent).

For all groups, five steps of grading were used for evaluation:

- 1: Clinically excellent/very good;
- 2: Clinically good;
- 3: Clinically sufficient/satisfactory;
- 4: Clinically unsatisfactory; and
- 5: Clinically poor.

This trial's primary focus is to evaluate the clinical properties, in terms of aesthetics, function and biology, of Cention-N alkasite material compared to glass ionomer cement. This is done through the FDI criteria universally used to evaluate direct dental restorations [24].

2. Materials and Methods

The present split-mouth, two-armed cohort study was designed and directed at the University of Pisa (Pisa, Italy).

Every procedure was conducted in accordance with the Declaration of Helsinki.

The protocol for this clinical investigation was approved by the ethics committee of Azienda Tutela Salute Sardegna (protocol 228/2020/CE, date of approval: 21 April 2020).

An informed consent was signed by the childrens' parents before any radiographical examination and procedures.

The 45 children included in the trial were to be treated in the Department of Pediatric Dentistry (S. Chiara hospital, Pisa, Italy).

The inclusion criteria were:

- Age of minimum 5 and maximum 9 years old;
- Children with an ASA score of I (healthy);
- A rating of at least 3 on the Frankl scale of behaviour [25]:
  - Frankl 3: Somewhat shy/reluctant child, but cooperative;
  - Frankl 4: completely cooperative child; and
- Presence of two carious primary molars, with no signs of necrosis, and one on each side of either the maxilla or the mandible. The caries had to be class II and affecting the same type of tooth functionally and anatomically speaking (e.g., both on primary molars, both on secondary molars). The ICDAS score of the caries had to be lower than five (visible dentin in a distinct cavity) The caries had to be lower than an ICDAS score of five (distinct cavity with visible dentin) [26];
- No spontaneous pain, infection, presence of fistulae, abscesses, swelling or pain upon percussion
- A radiographic evaluation was performed, including only teeth with a hypothetical time to physiological exfoliation of at least two years, showing a permanent tooth germ below the deciduous tooth and a normal-looking periodontal space and lamina dura.

The criteria for exclusion were as follows.

- Systemic pathologies affecting the patient;
- Development defects of teeth such as discoloration, anomalous anatomy and shape, excessive mobility; and
- Pulp exposure indicating the need for extraction or endodontic treatment.

To properly randomize the use of either material in the two groups, one in which the alkasite material (Cention-N, Ivoclar Vivadent AG, Liechtenstein) was used and one in which the glass ionomer cement (Fuji-IX, GC Europe) was used, and guarantee a bias-free evaluation of the restorations, a randomization procedure involving three operators was applied.

1. Cavities were numbered starting from the first quadrant and following a clockwise order.
2. To maintain the child's cooperation and prevent pain, local anesthetic was administered (lidocaine).
3. Isolation through a rubber dam was performed (Hygienic Medium Fiesta Dam H04641, Coltene, Altstätten, Switzerland).
4. A pediatric dentistry resident (Operator 1 or OP1), already trained to place either material on deciduous teeth, cleaned and prepared the cavities with a high-speed diamond round bur (Intensiv FGM 200, Intensiv, Collina D'oro, Switzerland) and a round cutter in tungsten carbide (D + z CB7.314 010).
5. In order to provide an adequate anatomic form, a ring matrix band made of metal (AutoMatrix, Dentsply, Konstanz, Germany) and a wedge had to be positioned between the cavity and the next (or previous) tooth.
6. Before the operative session, the preparation of two opaque envelopes containing indications to either use the glass ionomer cement or the alkasite material was assigned to Operator 2 (OP2). The envelopes were then sealed, and OP2 was to be blinded regarding which material is used for which cavity and was forbidden to enter the operating room. OP2 was involved in the evaluation procedure.
7. OP3 had the assignment of retrieving the envelopes, shuffle them in the presence of OP1 which then chose an envelope. The chosen envelope was then opened by OP3 and the material to use was told to OP1.

8. Restorations were made by OP1, using the chosen material for the first cavity and the other material for the second.
9. The height of the restorations was regularized by using a diamond turbine cutter (Intensiv FGM 254, Collina D'oro, Switzerland) to remove excessive contact points highlighted by an articulation paper and subsequently polished by using the Venus Supra polishing kit (Kulzer Italia, Milano, Italy).

OP2 (not involved in the operative appointment) performed the clinical and radiographical evaluation of every restoration at 3, 6, and 12 months by using the FDI criteria as a reference [24].

In order to correctly evaluate the aesthetic aspects of the restoration, the observation was made by using room light from a distance of minimum 60 and maximum 100 cm. If a restoration scored 4 or 5 it was considered a failure.

Regarding the statistical analysis, the following tests were used.

A Kruskal–Wallis nonparametric ANOVA test was used to compare the two materials at the different timepoints (T0–T4).

A Chi-square analysis was used to compare, with a significance level of $p < 0.05$ and $p < 0.01$, the "excellent" and "not excellent" scores for the two materials at the different timepoints.

A bivariate analysis was used to examine the effectiveness of both "time" and "material" factors on the number of "excellent" samples.

SPSS software (Chicago, IL, USA, ver. 22.0) was used for statistical analysis.

3. Results

A total of 45 children of a minimum age of 5 and a maximum age of 9 (mean age 6.15 ± 0.98 years), 17 males (37.8%) and 28 females (62.2%), were included (Table 1), with 112 primary molars presenting class II carious lesions. Of these, 59 were in primary first molars and 53 in primary second molars.

No dropouts were reported when the trial ended, and every patient adhered to the follow-up program.

Class II restorations made with the Fuji-IX GIC were performed on 55 deciduous teeth, either primary first molars or primary second molars.

Class II restorations made with the Cention-N alkasite material were performed on 57 deciduous teeth, either primary first molars or primary second molars.

Table 1. Distribution of gender and age.

	Average	**Standard Deviation (SD)**
AGE	6.1	0.99
	Male	**Female**
GENDER	17	28

Failure rates at 12 months were 2.1% for both groups, with two failed restorations for each group. Failures were because of a total restoration decementation, one reported at T1 (3 months) for both Fuji-IX GIC and Cention-N alkasite material, and another reported at T3 (12 months) for both materials (Table 2).

Table 2. Reported failures.

	Failures, n (%)			
	T0	**T1 (3 Months)**	**T2 (6 Months)**	**T3 (12 Months)**
Cention-N alkasite material	0(0)	0(0)	1(1.1)	2(2.2)
Fuji IX GIC	0(0)	0(0)	1(1.1)	2(2.2)

3.1. Aesthetic Properties

The report for the Cention-N alkasite material's aesthetic properties showed that, at T0, 55 restorations (100%) qualified as clinically excellent, while at T1 (3 months) 45 restorations (81.82%) qualified as clinically excellent and 10 (18.18%) as clinically good. At T2 (6 months), 30 restorations (54.55%) qualified as clinically excellent; 23 (41.83%) as clinically good, one (1.81%) as clinically sufficient, and one failure (1.81%) was reported. At T3 (12 months), 26 restorations (47.27%) restorations qualified as clinically excellent, 26 (47.27%) as clinically good, one (1.81%) as clinically good, and two failures were reported (3.63%) (Table 3).

The survey for the Fuji-IX GIC aesthetic properties showed that, at T0, 56 restorations qualified as clinically excellent (98.25%) and one (1.75%) as clinically good. At T1 (3 months), 37 restorations (64.91%) qualified as clinically excellent and 20 (35.08%) as clinically good. At T2 (6 months), 25 (43.85%) restorations qualified as clinically excellent, 31 (54.39%) as clinically good, and the first failure was reported (1.75%). At T3 (12 months), 20 restorations (35.09%) qualified as clinically excellent, 32 (56.14%) as clinically good restorations, three (5.26%) as clinically sufficient restorations, and the second failure was reported, for a total of two failed restorations (3.51%) (Table 3).

Table 3. Evaluation of aesthetic properties based on FDI criteria. T1 (3 months), T2 (6 months), T3 (12 months).

	Aesthetic Properties							
	Cention-N				GIC			
	n (%)				n (%)			
FDI CRITERIA	**T0**	**T1**	**T2**	**T3**	**T0**	**T1**	**T2**	**T3**
1—CLINICALLY EXCELLENT	55(100)	45(81.8)	30(54.55)	26(47.27)	56(98.25)	37(64.91)	25(43.85)	20(35.09)
2—CLINICALLY GOOD	0(0)	10(18.18)	23(41.83)	26(47.27)	1(1.75)	20(35.08)	31(54.39)	32(56.14)
3—CLINICALLY SUFFICIENT	0(0)	0(0)	1(1.81)	1(1.81)	0(0)	0(0)	0(0)	3(5.26)
4—CLINICALLY UNSATISFACTORY	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)
5—CLINICALLY POOR	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)
FAILED	0(0)	0(0)	1(1.81)	2(3.63)	0(0)	0(0)	1(1.75)	2(3.51)

The Kruskal–Wallis test indicated a statistically significant (K-W $p < 0.001$) decrease in the clinically excellent restorations made by using the Cention-N alkasite material, up to 47.27% at T3 (1 year).

Regarding "clinically excellent" Fuji-IX GIC restorations, a statistically significant (K-W $p < 0.001$) decrease, up to 35.09% at T3 (1 year) was also observed.

If the two materials are compared, a statistically significant difference favouring the Cention-N alkasite material was found at T1 ($p < 0.05$) whereas no statistically significant differences were observed at T2 and T3. Overall, there was no statistically significant differences in terms of aesthetic performance in a 12-month period between Fuji IX GIC and Cention-N alkasite material.

3.2. Functional Properties

The survey for the Cention-N alkasite material's functional properties showed that, at T0, 54 restorations (98.18%) qualified as clinically excellent and one (1.82% as clinically good, whereas at T1 (3 months) 48 restorations (87.27%) qualified as clinically excellent and seven (12.73%) as clinically good. At T2 (6 months), 40 restorations (72.73%) qualified as clinically excellent, 12 (21.81%) as clinically good, one (1.82%) as clinically sufficient, one (1.82%) as clinically insufficient but repairable, and one failure was reported (1.82%). At T3 (12 months), 40 restorations (72.73%) qualified as clinically excellent restorations, 11 (20.01%) as clinically good, two (3.63%) as clinically sufficient, and two (3.63%) failed restorations were reported (Table 4).

The survey for the Fuji IX GIC functional properties showed that, at T0, 53 restorations (92.98%) qualified as clinically excellent and four (7.02%) as clinically good, with the same data reported at T1 (3 months). At T2, 45 restorations (78.94%) qualified as clinically excellent restorations, nine (15.79%) as clinically good, one (1.75%) as clinically sufficient, and two failures (3.52%) were reported. At T3, 36 restorations (63.15%) qualified as clinically excellent restorations, 16 (28.07%) as clinically good, three (3.52%) as clinically sufficient, and 2 failures (3.52%) were reported (Table 4).

Table 4. Evaluation of functional properties based on FDI criteria. T1 (3 months), T2 (6 months), T3 (12 months).

	Functional Properties							
	Cention-N				GIC			
	n (%)				n (%)			
FDI CRITERIA	T0	T1	T2	T3	T0	T1	T2	T3
1—CLINICALLY EXCELLENT	54(98.18)	48(87.27)	40(72.73)	40(72.73)	53(92.98)	53(92.98)	45(78.94)	36(63.15)
2—CLINICALLY GOOD	1(1.82)	7(12.73)	12(21.81)	11(20.01)	4(7.02)	4(7.02)	9(15.79)	16(28.07)
3—CLINICALLY SUFFICIENT	0(0)	0(0)	1(1.82)	2(3.63)	0(0)	0(0)	1(1.75)	3(5.26)
4—CLINICALLY UNSATISFACTORY	0(0)	0(0)	1(1.82)	0(0)	0(0)	0(0)	0(0)	0(0)
5—CLINICALLY POOR	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)
FAILED	0(0)	0(0)	1(1.82)	2(3.63)	0(0)	0(0)	2(3.52)	2(3.52)

The functional properties of both materials have decreased over time, but no statistically significant difference was observed regarding the decrease in clinically excellent restorations between timepoints considering one material or the other. At different timepoints, no statistically significant differences were observed in terms of functional properties.

3.3. Biological Properties

The survey for the Cention-N alkasite material's functional properties showed that 55 restorations (100%) qualified as clinically excellent at T0, while at T1 (3 months) 53 restorations (96.36%) qualified as clinically excellent, and two (3.63%) as clinically good. At T2 (6 months), 52 restorations (94.55%) qualified as clinically excellent, two as clinically sufficient (3.63%), and one failure was reported (1.82%). Finally, at T3 (12 months), 51 (92.74%) restorations qualified as clinically excellent restorations, two as clinically sufficient restorations (3.63%), and two failed restorations (3.63%) were reported (Table 5).

The survey for the Fuji IX GIC functional properties showed that, at T0, 56 restorations (98.25%) qualified as clinically excellent and one (1.75%) as clinically good, whereas at T1 (3 months), 54 restorations (94.73%) qualified as clinically excellent and three (5.26%) as clinically good. At T2 (6 months), 54 restorations (94.73%) qualified as clinically excellent, one (1.75%) as clinically good, and two failures were reported (3.52%). At T3 (12 months), 52 restorations (91.23%) qualified as clinically excellent, three (5.25%) as clinically sufficient, and two failed restorations (3.52%) were reported (Table 5).

The biological properties of both materials have decreased over time, but no statistically significant difference was observed regarding the decrease in clinically excellent restorations between timepoints considering one material or the other. At different timepoints, no statistically significant differences were observed in terms of functional properties.

Table 5. Biological properties evaluation based on FDI criteria. T1 (3 months), T2 (6 months), T3 (12 months).

	Biological Properties							
	Cention-N				GIC			
	n (%)				n (%)			
FDI CRITERIA	**T0**	**T1**	**T2**	**T3**	**T0**	**T1**	**T2**	**T3**
1—CLINICALLY EXCELLENT	55(100)	53(96.36)	52(94.55)	51(92.74)	56(98.25)	54(94.73)	54(94.73)	52(91.23)
2—CLINICALLY GOOD	0(0)	2(3.63)	0(0)	0(0)	1(1.75)	3(5.26)	1(1.75)	0(0)
3—CLINICALLY SUFFICIENT	0(0)	0(0)	2(3.63)	2(3.63)	0(0)	0(0)	0(0)	3(5.25)
4—CLINICALLY UNSATISFACTORY	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)
5—CLINICALLY POOR	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)
FAILED	0(0)	0(0)	1(1.82)	2(3.63)	0(0)	0(0)	2(3.52)	2(3.52)

4. Discussion

Mesial and distal marginal ridges of primary teeth are different from permanent teeth. They are shorter (from occlusal surface to cervical margin), are more concave, and create a contact surface with adjacent teeth instead of a contact point. This makes it harder to obtain an adequate marginal seal and consequently prevent food impaction, therefore increasing the difficulty of class II direct restorations in deciduous teeth.

In addition to the anatomical differences between primary and permanent teeth, a wide variety of compliance (from completely compliant to no compliance at all) in patients aged 5 to 9 and a generally short attention span adds a time factor to an already difficult restorative procedure: specific formation and materials are then needed to work effectively and quickly.

It should also be noted that the usage of a rubber dam in patients aged 5 to 9 is considered difficult and depends heavily on the patient's level of compliance and the experience of the operator. Because a rubber dam is necessary with polymer-based materials and GIC is less sensitive to moisture, these materials needed to be compared for restorations made using a rubber dam.

In a systematic review from Dias et al. [27] class II restorations in primary teeth made by using either GIC or composite resin did not show any difference in performance, except for secondary caries in which GIC showed superior performance, probably due to the ability of the material to release fluoride ions.

In an in vitro study from Kini et al. [28] the alkasite restorative materials chosen as a comparison for this study was tested for microleakage against GIC and composite resin, showing that it had the lowest amount of microleakage after thermocycling.

Many of the studies evaluating alkasite materials and GIC are in vitro, and as such are hardly comparable to the present in vivo study.

The primary objective of this study is to compare the biological, functional, and aesthetic properties, over time, of class II restorations in primary teeth made with either Cention-N alkasite material or Fuji IX GIC.

Regarding aesthetic properties, the two materials behaved similarly with values getting worse over time by as much as 53% in the Cention-N group and 65% in the GIC group at the T3 follow up (12 months). Although there seems to be a difference in aesthetic performance between materials, no statistically significant differences between the two groups were observed. The striking worsening of aesthetic properties for both materials can be explained by the fact that, as already stated, class II restorations in primary teeth are often challenging, and pediatric patients often neglect cleaning interdental spaces. Class II restorations, in addition, are subjected to stronger forces and higher stress compared to other teeth.

Regarding functional properties, both materials showed signs of worsening at each timepoint, although to a lesser extent when compared to the aesthetic properties. The drop in scores observed for a single material was not significant, and the comparison between materials did not highlight any statistically significant differences. This result may be caused by the short follow-up time. Up to 12 months, however, the functional properties of Cention-N alkasite material and Fuji IX GIC seem to be comparable.

Regarding biological properties, both materials performed similarly, although a decrease of clinically excellent restorations over time was observed.

The failure rate was 2% at T3 (12 months) for both materials.

Some shortcomings of this study need to be addressed. Because other studies have reported a statistically significant difference between Cention-N and GIC, favouring the alkasite material [22], a longer period of observation with follow-ups at 2, 3, and 5 years are needed to confirm our results. Other trials with a higher number of samples may be needed, and a study design with calibrated and multiple operators might remove undetected biases caused by the presence of a single operator performing all the restorations. The presence of multiple operators might also help evaluating operator's skill and its influence on the performance of the two materials.

A comparison of the two materials used in restorations made without rubber dam should also be made, because, as already stated, not all patients are compliant with the use of a rubber dam. In addition, the two materials have different susceptibilities to moisture, so this comparison is needed to confirm whether the alkasite material shows the same performance as the GIC even in high-moisture environments.

A broader study including evaluation of the aforementioned operator skill and its effect on these materials' properties over time is part of the future objectives of our research team. In addition, observing the lost deciduous teeth through scanning electron microscope (SEM) technology might give interesting insights on the seal quality of the margins of both materials in class II restorations.

5. Conclusions

Based on the results of this study, the Cention-N alkasite material showed no differences in performance compared to Fuji IX GIC after one year of follow up. These encouraging results provide an alternative choice to the use of glass ionomer cements.

Longer follow-up results are needed, however, to confirm these findings. The choice of materials used for restoring deciduous teeth is only one part of conservative pediatric dentistry. Changes in lifestyle for both the child and his/her family and prevention are the other two parts needed for a functional and effective conservative dentistry.

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Data Availability Statement: The data supporting the results has been already included in the study "results" sections. Patient-specific data are not available due to privacy regulations.

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