Twenty-Four-Month Clinical Evaluation of A Newly Developed Zinc-Reinforced Conventional-Ionomer Cement in Primary Molars: Preliminary Study

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Abstract

Purpose: To evaluate the 2-year clinical results of a newly developed zinc-containing conventional glass-ionomer cement (ChemFil Rock, Dentsply) when used in occlusal and approximal restorations in primary molars with caries. Materials and Methods: Following caries removal and cavity preparation, the teeth were restored with ChemFil Rock. The restorations were evaluated at baseline and at 6, 12, 18, and 24 months according to the modified US Public Health Service (USPHS) criteria. Data obtained were analysed using the Mann-Whitney U-test and the Friedman test. Results: At the end of 24 months, the success rates of the occlusal and approximal restorations of the primary molars restored with ChemFil Rock were 100% and 69%, respectively. No post-operative sensitivity was reported in any restored tooth at any patient assessment time. Conclusion: These results suggest that this material is suitable for occlusal and approximal restorations in primary teeth and it demonstrated acceptable clinical results.

Key Words: Zinc-containing glass-ionomer, Primary molar, Clinical evaluation

Introduction

Tooth decay (caries) among children continues to be a major public health problem in both developed and developing countries globally [1]. Commonly used dental restoratives in paediatric dentistry today include glass-ionomer cements, polyacid-modified resin composites and resin composites. These materials are suitable for the preparation of tooth-substance-saving cavities [2].

Glass-ionomer cements (GICs) were developed by Wilson and McLean at the Laboratory of the Government Chemist in England in 1965. Fluoride ion release and uptake and the chemical adhesion to both enamel and dentin are the main advantages of GICs and have made them increasingly popular [3]. Other clinical advantages, such as biocompatibility and the low coefficient of thermal expansion, support their use in daily dental practice. Disadvantages of conventional materials included poor tensile and flexural strengths, which was precluded the use of these materials in load-bearing cavities, moisture sensitivity, and poor aesthetics, because of their opacity [4,5]. Since the introduction of GICs by Wilson and Kent, many modifications of these materials have been made over the years [3].

Today, a new generation of glass-ionomers may be able to provide better aesthetics, stronger bonding, and longer-term results, lasting years rather than months. GICs have been improved considerably in their aesthetic and mechanical properties. The development of GICs has been the subject of several studies due to the many advantages they provide [1,5-7].

Classical GIC powder consists of silica, alumina, calcium fluoride as the flux, cryolite, sodium fluoride, and/or aluminium phosphate [8]. One of the recently developed reinforced glass-ionomer material is ChemFil Rock (Dentsply DeTrey GmbH, Konstanz, Germany). According to the manufacturer, this new GIC has an enhanced setting reaction due to the zinc content as part of its glass particles, leading to higher strength, with similar working time and application comfort to regular GICs. Its zinc-modified reactive glass fillers achieve an earlier toughness build-up and superior fracture and wear resistance. The manufacturer also claims that this new restorative material requires significantly fewer steps than many competitive products (no cavity conditioning or surface coat needed). A simpler procedure can be a significant advantage in treating uncooperative or emergency patients or other challenging clinical situations (such as isolation).

The manufacturers of ChemFil Rock also suggest that this material is suitable for occlusal and approximal restorations in permanent and primary teeth [9]. In primary molars, several studies have shown that GICs are not recommendable for approximal cavities due to unacceptably high fracture rates. However, occlusal cavities may be restored [10-16].

Reviewing the literature, no reported study has addressed the clinical performance of the new GIC, ChemFil Rock for restorations in primary teeth.

Thus, the purpose of this study was to evaluate the 24-month clinical performance of the newly developed encapsulated zinc-containing glass-ionomer cement, ChemFil Rock, in occlusal and approximal cavities in primary molars. The hypothesis tested was that material would have acceptable effectiveness after 24 months of clinical service.

Materials and Methods

This study was conducted in the Department of Pediatric Dentistry, Faculty of Dentistry, Marmara University, Turkey. The study received ethical approval from Yeditepe University Human Ethics Committee (267/2012). The procedures and the risks and benefits of the study were explained to the child and the parents. Written informed consent was obtained from parents before proceeding with the study. The investigator was trained to perform the dental restorations under the supervision of an expert professor.

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Selection criteria

Ten children (five female, five male), ranging in age from 6 to 9 years (mean age 7.6 ± 0.84 years) who had been diagnosed with at least two non-cavitated carious lesions in the first and second primary molars with normal appearances and morphology and having antagonist natural teeth, were included in the study.

All children received information and instructions to improve their oral hygiene before operative treatment was performed. Children having behavioural problems, children with extremely poor oral hygiene, serious systemic diseases, and heavy bruxing habits were excluded from the study. None of the children dropped out the study.

Caries lesions in the selected sites were assessed by visual inspection and bitewing radiography. Visual inspections were performed with patients positioned in a dental chair with reflector light, air/water spray, and a plane buccal mirror using the visual-ranked method, developed by Ekstrand et al., under standardised conditions [17].

Bitewing radiographs were taken for the selected tooth using an intra-oral image plate (2+back, Dürr Dental, Germany) with an intra-oral X-ray machine (Belmont Photo-X II DC, Takara Belmont Corporation, Osaka, Japan). The teeth were assessed for the depth of the cavity and root length, and only if they had no pulpal exposure, no osseous changes, two-thirds of the root length present in the teeth, and the absence of any active periodontal disease and pain from the tooth were selected for the study. Otherwise, they were treated accordingly after informing their parents.

All examinations were performed independently on the same day by two clinicians (FEG and BD) who were calibrated before starting the study. Then, a decision was made regarding treating the tooth using minimally invasive techniques.

Restorative procedures

In total, 34 occlusal and approximal cavities in first and second primary molars were restored by the same operators. After conservative removal of enamel to open the cavity, Caries Detector (Sable Seek, Ultradent Products, Inc., USA) was applied to each cavity to identify the carious dentin visually. Carious dentin was removed using stainless steel burs (#8, #10, Medin, Czech Republic). Minimal cavities with no bevelling of the margins were prepared. The gingival wall was placed above the cemento-enamel junction. The operation field was isolated with cotton-rolls, dry-tips, and a saliva suction device. A thin matrix steel band (0.05 × 5.0 mm, Kerr Hawe SuperMat Adapt SuperCap Matrix System) and wooden wedges were used to protect adjacent teeth during approximal preparation. Air and water were used to wash, clean, and dry the cavities. Following cavity preparation, each cavity was restored with a newly developed zinc-reinforced glass-ionomer cement (ChemFil Rock A3, Dentsply De-Trey, Konstanz, Germany) according to the manufacturer's instructions [9].

Following removal of the matrix band and wedge, an occlusal adjustment, contouring, finishing, and polishing were completed under water-cooling with finishing burs (Dia-Burs, Mani Inc., Tochigi, Japan) and rubber cups (Polydentia SA, Switzerland) with low speed handpiece.

At least two restorations were placed in each patient, resulting in a total of 34 restorations. Of the 18 occlusal restorations, 8 were placed in upper primary molars and 10 in lower primary molars. Of the 16 approximal restorations, 6 were placed in upper primary molars and 10 in lower primary molars.

Clinical evaluation

A clinical evaluation of each restoration was performed by two investigators at baseline, 6, 12, 18, and 24 months using the modified USPHS criteria [18] *(Table 1)*. For each criterion, Alpha was used to indicate the highest degree of clinical acceptability. Bravo scores represented clinically acceptable scores, while a Charlie score indicated a clinically unacceptable score. Evaluations were made by two independent investigators not involved with the treatment procedures, using a mirror, explorer, and air stream. The investigators were calibrated to a predetermined level of inter- and intra-examiner agreement of at least 95% per single criterion. When differing evaluator decisions were noted for any restoration, a consensus decision was discussed and agreed upon during that recall period.

Table 1. Modified United States Public Health Service (USPHS) criteria.

Category	Scale	Criteria
Retention	Alpha	Present
	Bravo	partial loss but clinically acceptable
	Charlie	clinically unacceptable partial loss or absent
Secondary caries	Alpha	caries absent
	Charlie	caries present
Marginal adaptation	Alpha	continuity at the margin (no ledge or ditch)
	Bravo	slight discontinuity detectable with explorer but not requiring replacement
	Charlie	marginal ledge or crevice requiring replacement

Anatomic form	Alpha	anatomy resembles original restoration
	Bravo	anatomy shows change in contour but not requiring replacement
	Charlie	excessive wear with dentin exposure requiring replacement
Surface texture	Alpha	similar to polished enamel as determined by means of a sharp explorer
	Bravo	gritty or similar to a surface subject to a white stone or rougher than the adjacent tooth structure
	Charlie	pitting is sufficiently coarse to inhibit the continuous movement of an explorer across the surface
Marginal discoloration	Alpha	no discoloration on the margin
	Bravo	superficial discoloration on the margin
	Charlie	deep discoloration penetrated in a pulpal direction
Color match	Alpha	no mismatch to the adjacent tooth structure
	Bravo	slight mismatch but clinically acceptable
	Charlie	esthetically unacceptable mismatch
Postoperative sensitivity	Alpha	Absent
	Charlie	Present

Statistical analysis

Fisher's exact test was used to compare the occlusal and approximal cavity types and jaws in the same recall period for the various USPHS criteria at the 5% level of significance. The differences between groups were evaluated using the Mann-Whitney U-test, changes over time were assessed with the Friedman test (P=0.05). Statistical analyses were carried out using the InStat software (GraphPad Inc., San Diego, CA).

Results

Details regarding the GIC restorations are provided in *Tables 2 and 3*. Of the 34 total restorations, 20(59%) were placed in the lower jaw and 14(41%) in the upper jaw. All patients were available at all evaluation periods, resulting in a recall rate of 100%. The rates of A, B, and C scores obtained for the USPHS criteria, arranged by jaw and by time of occlusal restorations are shown in *Table 2* and those for approximal restorations in *Table 3*.

Table 2. *Results of clinical evaluation of occlusal restoration.*

		Retention			**Secondary caries**			**Marginal Adaptation**			**Anatomic Form**			**Surface Texture**			**Marginal Discoloration**			**Color Match**			**Postoperative sensitivity**		
Max I	n	A	B	C	A	-	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	-	C
Baseline	8	8	0	0	8	-	0	8	0	0	8	0	0	8	0	0	8	0	0	0	2	6	8	-	0
		100%			100%			100%			100%			100%			100%				25%	75%	100%		
6 m	8	8	0	0	8	-	0	8	0	0	8	0	0	8	0	0	8	0	0	0	2	6	8	-	0
		100%			100%			100%			100%			100%			100%				25%	75%	100%		
12 m	8	8	0	0	8	-	0	8	0	0	8	0	0	8	0	0	8	0	0	0	2	6	8	-	0
		100%			100%			100%			100%			100%			100%				25%	75%	100%		
18 m	8	8	0	0	8	-	0	8	0	0	8	0	0	8	0	0	8	0	0	0	2	6	8	-	0
		100%			100%			100%			100%			100%			100%				25%	75%	100%		
24 m	8	8	0	0	8	-	0	8	0	0	8	0	0	8	0	0	8	0	0	0	2	6	8	-	0
		100%			100%			100%			100%			100%			100%				25%	75%	100%		
Mand I	n	A	B	C	A	-	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	-	C
Baseline	10	9	1	0	10	-	0	9	1	0	10	0	0	10	0	0	10	0	0	0	3	7	10	-	0
		90%	10%		100%			90%	10%		100%			100%			100%						100%		

6 m	10	9 90%	1 10%	0	10 100%	-	0	9 90%	1 10%	0	10 100%	0	0	10 100%	0	0	10 100%	0	0	0	3 30%	7 70%	10 100%	-	0
12 m	10	9 90%	1 10%	0	10 100%	-	0	9 90%	1 10%	0	10 100%	0	0	10 100%	0	0	10 100%	0	0	0	3 30%	7 70%	10 100%	-	0
18 m	10	9 90%	1 10%	0	10 100%	-	0	9 90%	1 10%	0	10 100%	0	0	10 100%	0	0	10 100%	0	0	0	3 30%	7 70%	10 100%	-	0
24 m	10	9 90%	1 10%	0	10 100%	-	0	9 90%	1 10%	0	10 100%	0	0	10 100%	0	0	10 100%	0	0	0	3 30%	7 70%	10 100%	-	0
A: Alpha, B: Bravo, C: Charlie																									

Table 3. Results of clinical evaluation of approximal restorations.

		Retention			**Secondary caries**			**Marginal Adaptation**			**Anatomic Form**			**Surface Texture**			**Marginal Discoloration**			**Color Match**			**Postoperative sensitivity**		
Max II	n	A	B	C	A	-	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	-	C
Baseline	6	6 100 %	0	0	6 100 %	-	0	6 100 %	0	0	6 100 %	0	0	4 67%	2 33 %	0	6 100 %	0	0	0	0	6 100 %	6 100 %	-	0
6 m	6	3 50%	3 50 %	0	6 100 %	-	0	3 50%	3 50 %	0	4 67%	2 33 %	0	4 67%	2 33 %	0	6 100 %	0	0	0	0	6 100 %	6 100 %	-	0
12 m	6	2 33%	4 67 %	0	6 100 %	-	0	2 33%	4 67 %	0	3 50%	3 50 %	0	3 50%	3 50 %	0	6 100 %	0	0	0	0	6 100 %	6 100 %	-	0
18 m	6	2 33%	3 50 %	1 17 %	4 67%	-	2 33 %	2 33%	3 50 %	1 17 %	3 50%	2 33 %	1 17 %	3 50%	2 33 %	1 17 %	3 50%	3 50 %	0	0	0	6 100 %	6 100 %	-	0
24 m	6	2 33%	2 33 %	2 33 %	4 67%	-	2 33 %	2 33%	2 33 %	2 33 %	3 50%	1 17 %	2 33 %	3 50%	1 17 %	2 33 %	2 33%	3 50 %	1 17 %	0	0	6 100 %	6 100 %	-	0
Mand II	n	A	B	C	A	-	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	-	C
Baseline	10	10 100 %	0	0	10 100 %	-	0	10 100 %	0	0	10 100 %	0	0	10 100 %	0	0	10 100 %	0	0	0	0	10 100 %	10 100 %	-	0
6 m	10	6 60%	4 40 %	0	10 100 %	-	0	6 60%	4 40 %	0	8 80%	2 20 %	0	10 100 %	0	0	10 100 %	0	0	0	0	10 100 %	10 100 %	-	0
12 m	10	6 60%	3 30 %	1 10 %	8 80%	-	2 20 %	6 60%	3 30 %	1 10 %	7 70%	2 20 %	1 10 %	7 70%	3 30 %	0	9 90%	1 10 %	0	0	0	10 100 %	10 100 %	-	0
18 m	10	6	3	1	7	-	3	6	3	1	7	2	1	7	3	0	7	3	0	0	0	10	10	-	0

		60%	30 %	10 %	70%		30 %	60%	30 %	10 %	70%	20 %	10 %	70%	30 %		70%	30 %				100 %	100 %		
24 m	10	6	1	3	7	-	3	6	1	3	7	0	3	7	0	3	7	0	3	0	0	10	10	-	0
		60%	10 %	30 %	70%		30 %	60%	10 %	30 %	70%		30 %	70%		30 %	70%		30 %			100 %	100 %		
A: Alpha, B: Bravo, C: Charlie																									

Retention

None of the occlusal restorations was lost during the 24-month study period, resulting in a retention rate of 100%. Only one restoration was partially lost in the lower jaw at 24 months, resulting in a retention rate of 90%. No significant difference in retention rate was observed between the jaws (p=0.999).

The failure rate after 24 months was 31% for approximal restorations. Two restorations in the upper jaw and six restorations in the lower jaw from the approximal restoration group were rated A at 24 months; no difference was observed between the jaws (p=0.608).

Significant differences in the retention rate were observed between the two cavity types in the upper jaw (p=0.015), but there was no significant difference in the lower jaw (p=0.303) (*Tables 4 and 5*).

Table 4. Differences between cavity preparations in the maxilla.

Maxilla	Retention	Marginal adaptation	Anatomical form	Surface texture	Marginal discolouration
Approximal Restorations /Occlusal Restoration	0.015	0.015	0.05	0.05	0.015

Table 5. Differences between cavity preparations in the mandibula.

Mandibula	Retention	Marginal adaptation	Anatomical form	Surface texture	Marginal discolouration
Approximal Restorations /Occlusal Restoration	0.303	0.303	0.215	0.21	0.21

Secondary caries

No secondary caries was detected in association with any occlusal restoration after 2 years. Only two cases of secondary caries were observed in the upper jaw and three in the lower jaw after 24 months. There was no significant difference between the groups ($p > 0.05$).

Marginal adaptation

For marginal adaptation, all restorations in the upper jaw were rated A and only one restoration was rated B in the lower jaw in the occlusal group after 24 months. No difference was observed between the jaws (p=0.999). Two restorations in the upper jaw and six in the lower jaw were rated A in the approximal group after 24 months, and no difference was observed between the jaws (p=0.6084). Significant differences in marginal adaptation were observed between the two cavity types in the upper jaw (p=0.015), but there was no significant difference in the lower jaw (p=0.303) (*Tables 4 and 5*).

Anatomical form

Regarding anatomical form, 100% of the occlusal restorations showed no anatomical form loss at 24 months (p=1.0). Three restorations in the upper jaw and seven in the lower jaw had no anatomical form loss in approximal restorations at the end of 24 months (p=0.606). There were significant differences in anatomical form between the two cavity types in the upper jaw (p=0.05), but no significant difference in the lower jaw (p=0.215) (*Tables 4 and 5*).

Surface texture

Surface texture was scored as A for all occlusal restorations in the first evaluation period. Three restorations in the upper and seven restorations in the lower jaw were scored as A at 24 months (p=0.060). Differences in surface texture ratings between occlusal and approximal restorations were found to be statistically significant in the upper jaw (p=0.05), but not in the lower jaw (p=0.21) (*Tables 4 and 5*).

Marginal discolouration

No generalised discolouration was detected in the occlusal restorations at any evaluation period. Two restorations in the upper jaw and seven restorations in the lower jaw were rated A in the approximal restorations at 24 months (p=0.99). Differences in marginal discolouration ratings between occlusal and approximal restorations were found to be statistically significant in the upper jaw (p=0.015), but not in the lower jaw (p=0.21) (*Tables 4 and 5*).

Colour match

Colour match was scored as C for all approximal restorations and none of the occlusal restorations was scored as A at any evaluation period. There was no significant difference in the colour match scores between the two cavity types or the two jaws ($p > 0.05$).

Postoperative sensitivity

Postoperative sensitivity was absent in all patients. No statistically significant difference was found among the cavity types groups in any of the evaluation criteria at any recall time ($p > 0.05$).

Discussion

Glass-ionomer cements have been the subject of numerous studies regarding their clinical performance. This study was performed to evaluate the 2 year clinical performance of a newly developed zinc-containing conventional glass-ionomer cement when used in occlusal and approximal restorations in primary molars with occlusal or approximal caries. The rationale for using this material was that it has an enhanced setting reaction, due to the zinc content of its glass particles, leading to higher strength, with similar working time and application comfort to regular GICs. Its zinc-modified reactive glass fillers achieve an earlier toughness build-up and superior fracture and wear resistance. This new restorative material also requires significantly fewer steps than many competitive products (no cavity conditioning or surface coat needed) [9]. A simpler procedure can be a significant advantage for treating uncooperative children or emergency patients or other challenging clinical situations, such as isolation and less readily accessible areas in the mouth.

The restorations of the present study were placed in mixed dentition at ages of 6-9 years, with good cooperation and a quite long period of clinical service until exfoliation. This simulated realistic clinical conditions in paediatric dentistry.

Because no data are yet available on the long-term clinical behaviour of this recently developed zinc-containing conventional glass-ionomer cement in occlusal and approximal restorations, we cannot readily compare our results with those of other studies. In the literature, different criteria have been used for determining success and failure of restorations. In the present study, restorations were rated using the modified USPHS criteria, according to Daou et al., Kim et al., and Yazici et al. [6,18,19].

The results of this study are comparable with those of Krämer and Frankenberger, who showed that using a condensable metal-reinforced glass-ionomer cement to restore primary molars, the 2year survival rate was 92% for occlusal restorations and 66% for approximal restorations [13]. In this study, the newly developed zinc-containing conventional glass-ionomer cement (Chemfil Rock) showed a 100% retention rate for occlusal and 69% for approximal restorations during the 24-month study period. All failed or clinically unacceptable restorations with scores of 'Charlie' after 24 months were attributed to approximal cavities. Many studies have shown that multiple surface restorations generally have lower survivals than single surface restorations [6,20,21]. This was also seen in this study, in that approximal restorations showed more failures than occlusal restorations in the upper jaw. The main reasons for failure of Chemfil Rock in the present study were total loss of retention and secondary caries.

Results from a study that included 46 glass-ionomer restorations indicated that secondary caries was the reason for failure of 13-17% of glass-ionomer restorations [6]. This is consistent with the present study, in which no significant difference was found with regard to secondary caries among all groups with Chemfil Rock restorations at 24 months. Additionally, the benefits of fluoride release from glass-ionomer restorations with regard to cariostasis are unclear. Further longer-term studies are needed to more fully quantify the cariostatic effect of glass-ionomer restorations placed in load-bearing cavities.

Anatomical form and surface texture showed 100% Alpha for occlusal and 62% Alpha for approximal restorations, which is related to the glass-ionomer cement used. The incorporation of reactive glass fillers modified with zinc oxide, which are easily released from the matrix, as well as the increased itaconic acid in the liquid of Chemfil Rock, may explain the resistance of this new glass-ionomer cement [22]. The evaluations of anatomical form and wear were subjective, relying on the examiner's assessment in determining whether the anatomical form had changed over time; this is clearly a limitation of the study. The method was qualitative and of course could not produce the precise quantification provided by other methods of wear analysis, such as the indirect cast comparison method [23]. Nevertheless, our subjective results were supported by the findings of other authors who used indirect evaluations [6].

The material tested, Chemfil Rock, exhibited continuous marginal adaptation for occlusal cavities over the length of the study, as shown by the proportion of Alpha scores (continuity at the margin, no ledge or ditch), which was 94% at 24 months. The worst outcomes (Charlie scores, marginal ledge or crevice requiring replacement) were 31% for approximal cavities after 24 months. These results differ from one study that reported 60.9% Alpha scores and 8.7% Charlie scores for a high-viscosity glass-ionomer cement (Fuji IX) after 2 years [6]. Regarding postoperative sensitivity, no patients suffered from pain in occlusal or approximal restorations after 24 months.

The small number of restorations for evaluation at the 2-year recall may have masked differences that could have been detected if a greater number of restorations had been evaluated.

Conclusion

Glass-ionomer cement is often used as a biomimetic material, because of its similar mechanical properties to dentin. This, together with the important benefits of adhesion and the release of fluoride, make it an ideal material in many restorative situations. The results suggest that the material tested, ChemFil Rock, is suitable for use in occlusal and approximal restorations in primary teeth.

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