



Clinical evaluation of a glass ionomer cement in primary molars

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Abstract

Purpose: The aim of the study was to evaluate the clinical performance of a high powder:liquid ratio self-cure glass ionomer cement in the restoration of primary molars.

Methods: Fuji IX GP (GC International, Tokyo, Japan) was used to restore 129 carious cavities (56 1-surface; 73 2-surface) in 69 patients of mean age 6 y 7 mo. Approximal cavities were prepared with a slot only design, and all cavities were small to medium in size. Restorations were evaluated at 6 mo, 1 y and 2 y using USPHS criteria, and the survival rate calculated using survival analysis.

Results: The cumulative survival rate of single-surface restorations was 100 percent at 2 y, and of 2-surface restorations was 99 percent at 6 months and 1 year, and 93 percent at 2 y. All failures were due to loss of restoration. The overall USPHS alpha ratings at 2 y were: marginal discoloration, 96 percent; anatomic form, 100 percent; marginal adaptation, 99 percent. There was no incidence of secondary caries.

Conclusions: A high powder:liquid ratio glass ionomer cement was successful over 2 years in the restoration of small-medium sized cavities in primary teeth. It is predictable that the performance will continue to be highly satisfactory over the next 2-3 years. (*Pediatr Dent* 22:486-488, 2000)

For many years amalgam was the material of choice for the restoration of primary molars. However, there has been some concern expressed recently regarding the use of amalgam in children. In addition, adhesive tooth-colored materials have become available and their properties and adhesive potential have steadily improved. One such material is glass ionomer cement, which has the advantages of high fluoride release and chemical adhesion, compared to resin-based materials.

Glass ionomer cements were introduced into dentistry in the 1970s. However, the early materials lacked strength and did not perform well in stress-bearing areas in primary teeth. Subsequently, a silver-modified glass ionomer (ceramic-metal; "cermet") was marketed (Ketac Silver; Espe Dental, Seefeld, Germany), and clinical trials of this material in primary teeth were reported.¹⁻⁷ The results were equivocal, however, the consensus appeared to be that cermet was not satisfactory in large cavities or when subject to high occlusal stress.

Resin-modified glass ionomers have also been evaluated in primary teeth.^{8,9} Whereas Croll⁸ reported no failures after 12-18 months, Folkesson et al.⁹ found 20 percent failure after 3 years, mainly due to secondary caries and loss of retention. However, different products were used.

Capsulated, high powder:liquid ratio, self-cure glass ionomer restorative cements are now available, e.g., Chemflex (Dentsply, York, PA), Fuji IX GP (GC International, Tokyo, Japan) and Ketac Molar (Espe). Although these products have

been termed 'condensable' because of their high viscosity on delivery from the capsule, this is not correct within the strict meaning of the word. Their mechanical properties are higher than their predecessors. For example, according to the manufacturers, Fuji IX GP has a 2-h compressive strength of 182 MPa compared to 154 MPa for Fuji II (GC International), and Ketac Molar has a 24-hour compressive strength of 230 MPa compared to 170 MPa for Ketac Fil.

The aim of the present study was to evaluate the clinical performance of Fuji IX GP in primary molars over 3 years. The 2-year data are reported here.

Methods

Sixty-nine patients of the Oral Health Education Unit, Brisbane, between the ages 5 – 8, (mean age 6 y 7 mo), took part in the study. The procedures, risks, and benefits were explained to the parents and informed consent received. The study received the approval of the Ethics in Clinical Research Committee, School of Dentistry, University of Queensland. The restorations were placed as part of the overall treatment plan for the patients, and were placed by one of the authors (JR). A total of 129 cavities (56 1-surface, 73 2-surface) was restored. Criteria for inclusion in the study were that the patient required the restoration of small to medium-sized occlusal and approximal carious lesions in primary teeth, and that the teeth would be available for 3-y follow up. Patients who had a medical history which would compromise treatment or outcome were excluded.

Local anesthesia was only administered if the patient experienced discomfort during the initial stages of cavity preparation. For both occlusal and approximal cavities, access was gained through the overlying tooth structure with a high-speed handpiece under air/water spray. For approximal lesions in which the marginal ridge had been destroyed, access was gained directly into the carious lesion. The teeth were made caries-free using rotary and hand instruments, ensuring minimal removal of sound tooth structure. The final outline of the preparation was dictated by the position and extent of the initial caries. The cavity preparation for approximal lesions did not include an occlusal dovetail.

Following preparation, the cavity was washed and dried. For approximal cavities prepared without local anesthesia, topical anesthetic was applied to the gingival tissues. The dentin was conditioned for 20 s with a solution of 10 percent polyacrylic acid (Dentin Conditioner; GC International). Cavities were washed with air/water spray for a few seconds, and dried with compressed air taking care not to desiccate the dentin. For approximal cavities, a Tofflemire matrix band was lightly coated with a low-viscosity unfilled resin (Fuji Coat LC; GC International), placed around the tooth, tightened and wedged if

Table 1. Restorations Evaluated

Time interval	Number entering time interval	Number evaluated		Teeth exfoliated		Lost to study (patient not available)		Restorations lost		Cumulative failure (%)	
		1- Surface	2-Surface	1- Surface	2-Surface	1- Surface	2-Surface	1- Surface	2-Surface	1- Surface	2-Surface
Baseline-6 mos.	129	54	72	-	-	2	1	-	1	0	1.4
6 mos.-1 year	125	48	65	1	3	5	3	-	-	0	1.4
1 year-2 years	113	38	63	1	1	9	1	-	3	0	6.6

necessary. Teeth were isolated with cotton rolls and a saliva ejector, Fuji IX GP mixed for 10 s in a mixing machine (Ultram; Southern Dental Industries, Bayswater, Australia), and injected directly into the cavity. The unset material was manipulated into shape with hand instruments in order to minimize the need for finishing and polishing. After 4 min, the restoration was coated with a thin layer of Fuji Coat LC and photopolymerized for 10 s with a curing light (Visilux; 3M Dental, St Paul, MN).

For approximal lesions, the matrix band was carefully removed in order to prevent gingival hemorrhage and the occlusion checked with articulating paper. Occlusal adjustments were made if necessary with rotary instruments, taking care to avoid heat generation. If adjustment had been carried out, a further coat of Fuji Coat LC was applied and photocured.

Restorations were evaluated after placement (base line), 6 mo, 1 y, and 2 y using United States Public Health Service (USPHS) criteria.¹⁰ If any restorations failed according to these criteria, a survival analysis was carried out. In addition, approximal restorations were evaluated for integrity of contact area as follows: A1 – firm resistance to floss; A2 – light resistance to floss; A3 – no resistance to floss; B – no visible evidence of approximal contact; H – approximal contact not required. Photographs were taken at 1:1 magnification on color slide film at each evaluation.

Results

The number of restorations evaluated at each time interval, the reasons for non-evaluation, and the cumulative failure rates (due to restoration loss) are shown in Table 1. The percent USPHS “alfa” ratings for marginal discoloration and marginal adaptation are given in Table 2. The only failures were the loss of one 2-surface restoration between base line and 6 months, and the loss of three 2-surface restorations between 1 and 2 y, equating to a cumulative 2-y failure rate of <7 percent. The overall percent USPHS “alfa” ratings were; marginal discoloration, 96 percent; anatomic form, 100 percent; marginal adaptation, 99 percent. There was no secondary caries. For approximal restorations, 94 percent were scored A1 for contact area at 2 y.

Discussion

Welbury et al.¹¹ compared amalgam and a self-cure glass ionomer (Ketac Fil; Espe Dental, Seefeld, Germany) in primary teeth over 5 years. Eight Class I and 111 Class II cavities were restored with glass ionomer, and the overall cumulative failure rate was approximately 50 percent at 2 years. It appears that most failures were due to restoration loss. Cavity

preparation for glass ionomer involved only removal of any existing restoration and caries, however, the cavity sizes were not given except to report that the average area was 16 percent of the occlusal surface. In a 3-year clinical study of another self-cure glass ionomer (Chemfil; Dentsply, UK),¹² a failure rate of 60 percent was reported, compared to 8 percent for amalgam and 16 percent for resin composite. “Small, standard” Class II cavities were prepared, and the main cause of failure was isthmus fracture. In another amalgam/glass ionomer comparison,¹³ an overall 3-year failure rate of 37 percent of 515 Ketac Fil restorations was reported. Significantly more Class II than Class I ionomers failed, the main reason again being restoration fracture.

The influence of cavity form in the restoration of approximal caries with glass ionomer cement in primary teeth has also been evaluated.¹⁴ “Microcavities,” involving only removal of caries, were compared with modified Black’s Class II cavities (with a broad isthmus). After 3 years, the cumulative failure rate was 25 percent for the microcavities and 32 percent for the modified Black’s cavities, which was not significantly different.

It appears from the above studies that the main reason of failure of self-cure glass ionomers, particularly in posterior approximal cavities, is fracture due to their inadequate strength. This has prompted clinical evaluations of glass ionomer formulations which potentially have improved physical properties. A “cermet” (ceramic-metal) material (Ketac Silver; Espe) is commonly assumed to have significantly better mechanical properties than its conventional counterpart Ketac Fil. However, according to the manufacturers, their tensile strengths are the same at 15 MPa, and the compressive strength of Ketac Silver is only 12 percent higher than that of Ketac Fil (190 MPa and 170 MPa respectively). In contrast, one independent study¹⁵ has reported 24-h tensile strengths of 14.0 MPa and 12.9 MPa, and 24-h compressive strengths of 152 MPa and 113 MPa, for Ketac Fil and Ketac Silver respectively. Flexural strength and flexural modulus have been shown by Peutzfeldt.¹⁶ to be not significantly different; the flexural strengths of Ketac Fil and Ketac Silver were 2.7 MPa and 1.4 MPa respectively, and for flexural modulus were 25 MPa and 29 MPa.

Table 2. USPHS ‘Alfa’ ratings (%)

	Marginal discoloration			Marginal adaptation		
	1-surface	2-surface	Total	1-surface	2-surface	Total
Baseline	100	100	100	100	100	100
6 months	100	100	100	100	100	100
1 year	100	100	100	100	98	99
2 years	90	100	96	100	98	99

Table 3. Contact Area Ratings (%)

	Ratings*	
	A1	A2
Base line	100	0
6 months	96	4
1 year	92	8
2 years	95	5

*excluding 'H' ratings, A1= firm resistance to floss.
A2= light resistance to floss.

Two groups^{3,5} have compared Ketac Fil with Ketac Silver in the restoration of primary molars. In the first study,³ two approximal cavity designs were used; with or without a dovetail. The results suggested that neither a particular material nor a particular cavity design was preferred. After 5-14 mo, the failure rates of Ketac Fil and Ketac Silver were 16 percent and 23 percent respectively, and the failure rates in cavities with and without a dovetail were 19 percent and 21 percent respectively. No cross-tabulation of material versus cavity type was reported. The authors³ proposed that glass ionomer was a useful alternative to amalgam, in small cavities not subjected to strong biting forces. The failure rate in the second (2.5 year) study⁵ was significantly higher for Ketac Silver (41 percent) compared to Ketac Fil (24 percent). The main difference between the two materials in this study⁵ was the greater deterioration in anatomic form and marginal integrity of Ketac Silver. Cavities for neither material included an occlusal dovetail. The authors suggested that the higher loss rate of Ketac Silver may have been due to its lower bond strength, however, it may also have been due to the lower mechanical properties of Ketac Silver as reported by Cattani-Lorente et al.¹⁵ The authors⁵ proposed that Ketac Fil has potential in pediatric dentistry, but not Ketac Silver.

Ketac Silver has also been evaluated in primary teeth either alone,⁶ with amalgam,^{2,4} or with a resin-modified glass ionomer.⁷ Only one publication² suggested that Ketac Silver was acceptable in primary teeth, and then only in restorations with little occlusal stress.

An overall failure rate of <7 percent in the present study is substantially better than that found in all other studies on conventional self-cure glass ionomer cement, and may be due to case selection, technique or material. All restorations were small to medium in size, and would therefore be expected to be carrying minimal stress. No occlusal dovetail was placed, which eliminates the possibility of isthmus fracture. Strict attention was paid to moisture control, in order to prevent damage to the cement by saliva. The mechanical properties of Fuji IX GP may be superior to those of the self-cure glass ionomer cements (predominantly Ketac Fil) used in previous studies. However, only flexural strength comparisons have been published;¹⁶ values for Ketac Fil, Ketac Silver and Fuji IX were 25 MPa, 29 MPa and 30 MPa respectively, which were not statistically different.¹⁶ Comparative compressive and tensile strength data from a single laboratory do not appear to be available. However, the manufacturer's data show that Fuji IX GP (P:L = 3.5:1), has a 1-d compressive strength of 220 MPa and a 1-d tensile strength of 22 MPa. Comparative data for Fuji II, a self-cure restorative glass ionomer, are: P:L = 2.7:1; compressive strength 202 MPa; tensile strength 16 MPa. Unfortunately there do not appear to be any clinical compari-

sons of Fuji II and Fuji IX in primary molars which might clarify the mechanical properties/clinical survival relationship.

The results of 3-year follow up will be reported in the future.

Conclusion

It is concluded that the high powder:liquid ratio self-cure glass ionomer cement Fuji IX GP is suitable for the restoration of small to medium-sized approximal and occlusal cavities in primary molars for a 2-year period. The results suggest that Fuji IX GP can be considered a viable restorative material in such cavities for periods longer than 2 years.

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