A Retrospective Study of the 3-Year Survival Rate of Resin-Modified Glass-Ionomer Cement Class II Restorations in Primary Molars

Mark Webman*/ Ezat Mulki**/ Rosie Roldan***/ Oscar Arevalo****/ John F Roberts*****/ Franklin Garcia-Godoy******

Objective*: To determine the three-year survival rate of Class II resin-modified glass-ionomer cement (RMGIC), Vitremer, restorations in primary molars and to compare these results with measurements of survival of Class II restorations of standard restorative materials.* ***Study Design****: Data on Class II restorations placed in primary molars during a six-year period were collected through a chart review and radiographic evaluation in the office of a board-certified pediatric dentist. A radiograph showing that the restoration was intact was required at least 3 years after placement to qualify as successful. If no radiograph existed, the restoration was excluded. If the restoration was not found to be intact radiographically or was charted as having been replaced before three years it was recorded as a failure. The results of this study were then compared to other standard restorative materials using normalized annual failure rates.* ***Results:*** *Of the 1,231 Class II resin-modified glass-ionomer cement restorations placed over six years 427 met the inclusion criteria. There was a 97.42% survival rate for a 3-year period equivalent to an annual failure rate of 0.86%.* ***Conclusions****: A novel approach comparing materials showed that in this study Vitremer compared very favorably to previously published success rates of other standard restorative materials (amalgam, composite, stainless steel crown, compomer) and other RMGIC studies.*

Key Words: Dental restoration failure, Dental materials,Glass-ionomer cements,Survival analysis,Dental cavity preparation.

INTRODUCTION

One of the challenges that practicing dentists face everyday is to decide which dental material is best suited for each particular situation. The field of pediatric dentistry provides its own set of challenges, as restorations need to be completed in an expedient manner, frequently in less than ideal conditions. Although its market share has sharply decreased, especially in developed countries, amalgam continues to be the standard for restoring primary molars. It has provided a predictable, long-term solution for most restorative situations although it is not without problems and controversies. Amalgam requires a retentive preparation which is more aggressive than is required for bonded restorations. Furthermore, the need to extend the preparation into caries-susceptible grooves increases the size of the preparation. The esthetics is not optimal; amalgam is initially silver in color and then undergoes corrosive changes which make it appear dark gray or black. In addition, a "social" controversy exists concerning the safety of the material due to its mercury content .[1-3]

In the early 1970's, McLean and Wilson[4] developed glass polyalkenoate cement, also known as "glass-ionomer." These cement systems are based on polycarboxylate and silicate materials. The early glass-ionomers offered several advantages for use in children. They were tooth colored, chemically bonded to tooth structure, and

*Mark Webman, DDS, Adjunct faculty member at Miami Children's Hospital and full-time private practice South Miami, FL.
**Ezat Mulki, DMD, Former resident in pediatric dentistry Miami Children's Hospital now private practice Atlanta, GA.
***Rosie Roldan, DMD, MD, Director, Pediatric Dental Residency Program, Miami Children's Hospital.
****Oscar Arevalo, DDS, ScD, MBA, MS, Assistant Director, Pediatric Dental Residency Program, Miami Children's Hospital.
*****John F Roberts, BDS, Private practice London, England.
******Franklin Garcia-Godoy, DDS, MS, PhD, PhD, Senior Executive Associate Dean for Research, University of Tennessee, College of Dentistry.

Send all correspondence to:

Mark Webman
6601 SW 80 St.
Suite 212
South Miami, FL 33133
Phone: 305 666-2068
Fax: 305 666-0612
E-mail:msweb@bellsouth.net

released substantial amounts of fluoride for uptake by adjacent tooth structure. However, glass-ionomers did not compare to amalgam in compressive strength, fracture strength or wear resistance. In 1987, manufacturers added a small quantity of a polymerizable resin composite to conventional glass-ionomer to create a resin-modified glass-ionomer cement (RMGIC) intended to be a lining material (Vitrabond [name changed to Vitrebond]-3M ESPE, St. Paul, MN). In the early 1990s, manufacturers followed with restorative RMGIC's (Vitremer, 3M ESPE and Fuji II LC, GC America Alsip, IL). This new class of restorative materials had the advantages of a conventional glass-ionomer as well as wear and fracture resistance necessary to be used for restoration of teeth having certain types of carious lesions, fractures and enamel or dentin malformations. Vitremer (Vitremer Core Buildup/Restorative material, 3M ESPE)[5] and other RMGIC's differ from other direct application tooth-colored restorative materials in that they are:

- Fluoride releasing and rechargeable
- Able to chemically bond to dentin
- Biocompatible
- Tri-cured, three hardening reactions (resin/chemical, resin photopolymerization, the glass-ionomer acid-base setting reaction)
- Similar to tooth structure in the coefficient of thermal expansion
- Available in various tooth colored shades

In 1997, Donly and Nelson[6] showed that these materials release a significant amount of fluoride. They found that 2.05 ±0.24 ppm of fluoride was released from the restoration up to 28 days after the placement when a fluoridated dentifrice was used daily. Researchers who explored the remineralization effect of this fluoride release found histologically that less demineralization occurred at the tooth-restoration interface with RMGIC materials than in amalgam restorations.[7, 8] The significant fluoride release and decrease in demineralization results in less potential for secondary caries.[9]

There have been very few studies with large datasets documenting the clinical success of Vitremer or any other RMGIC. Croll *et al*[10] published one such study with similar conditions to the present study. Their retrospective study used Vitremer in the private practice of a pediatric dentist. The study included 406 Class II restorations and 393 Class I restorations. The authors found an overall success rate of 93% for all Vitremer restorations placed in this office over a three-year period.

The purpose of the current study was to retrospectively determine the clinical success of a RMGIC restorative material (Vitremer) used in Class II restorations in primary teeth in a private office setting of one board certified pediatric dentist and to compare the results of this study to other studies on survival of restorations in primary teeth.

MATERIALS AND METHOD

The Miami Children's Hospital Institutional Review Board approved this study on August 8, 2012 (#1-729660-1).

Within the limitations of a typical pediatric dental practice with the usual amount of behavior problems and parental concerns, the following technique was used for restorations reported in the study. All restorations were done by the same board certified pediatric dentist (MW) who was the sole determiner of whether a restoration needed to be replaced or not during the time period of the study.

> Nitrous oxide/oxygen analgesia and local anesthesia were used for restorations. A rubber dam was placed to isolate the tooth using the slit-dam technique. A high-speed water-cooled #330 carbide bur was used for initial tooth preparation followed by debridement of carious tooth structure as necessary with a #4 round carbide bur and/or spoon excavator. An enamel hatchet was often used to refine the gingival floor of the preparation. A box preparation was used for all restorations. When the decay involved the occlusal surface a separate occlusal restoration was cut unless the two lesions connected. After the preparation was completed it was cleaned with water/air spray, air-dried, and inspected for decay and pulp exposure, as well as to ensure correct outline form. A straight T-band (Pulpdent, Watertown, MA) was placed as a matrix and one or two interdental wedges were placed. The preparation was again washed and dried. Vitremer Primer was placed on all surfaces and air-dried. It was not polymerized at that time. Vitremer was mixed according to manufacturer's instructions and placed in bulk using a Centrix syringe (Centrix Dental, Shelton, CT). Using an alcohol dipped gloved finger the material was compressed and smoothed. Excess was removed using an explorer. The material was exposed to a calibrated curing light for 40 seconds. The tooth surface and restoration were etched with 37.5% phosphoric acid gel (Ultradent, South Jordan, UT) for 15 seconds. The area was washed, dried and primed with Scotchbond Multipurpose primer (ESPE 3M), then air-dried and sealed (Ultraseal XT, Ultradent tooth colored sealant). The T-band and wedges were removed and the restoration trimmed and refined using a #8 round bur, a #7901 flame 12-bladed finishing bur (Midwest), and a gapped finishing strip (3M). The contact was checked with dental floss and occlusion adjusted as needed.

Data collection took place at a private pediatric dental office (MW) where a chart review including evaluation of radiographs was conducted by an independent observer (EM). The data was entered, tabulated and analyzed, utilizing Excel (Microsoft Office, 2010). Information on RMGIC (Vitremer) Class II restorations placed in the office from January 1, 2002 through December 31, 2008 was collected. The selection of subjects did not discriminate based on age, race or gender. Vitremer had been used in this office since 1994 but radiographs prior to 2005 were lost due to a natural disaster that limited the timeline of the investigation. The following data were collected:

1. Age of patient at time of restoration placement
2. Tooth restored
3. Surfaces restored
4. Date of radiograph taken at least 3 years post-placement
5. Age of patient at last radiograph that shows restoration in place.

Based on the chart review and the radiographic evaluation, the restorations were categorized as failure, success or exclusion. A restoration was judged to be a failure if it needed to be replaced or the tooth extracted because of pathosis related to the restoration before 3 years had elapsed after initial placement. To be included in the study and judged successful the patient must have had at least one radiograph of the tooth with the restoration present and functional 3 years or more after placement. Teeth were excluded from the study if:

1. They were lost less than 3 years after placement, due to pathosis not related to the restoration or due to natural exfoliation.
2. They were extracted prior to 3 years for orthodontic reasons.
3. The subject restoration was replaced or incorporated into a new restoration or stainless steel crown because of pathosis (caries or a fracture of the tooth) remote from the subject restoration.
4. There was no radiological follow-up 3 years or more after the placement of the restoration.

Survival rate of Vitremer (RMGIC) restorations in this study were compared to other multi-surface restoration studies utilizing Hickel *et al's* [11] meta-analysis of longevity of occlusally stressed restorations in primary posterior teeth. Hickel's data was reformatted to include only Class II restorations. Hickel calculated the "annual failure rates" for each study in the meta-analysis by dividing the percent of restorations that failed during a study by the number of years of the study. This data was then analyzed using Burke *et al's* "normalized annual failure rate"[12] which allows comparison of the longevity of dissimilar restorative materials in permanent teeth. In an attempt to adapt Burke's formula to be used in studies in the primary dentition a modification of Burke's criteria for application was made. While Burke required a minimum duration of each study to be 3 years, in the present study a 2-year minimum was adopted. Using this revised criterion, "normalized failure indexes" were calculated for amalgam, composite, compomer and RMGIC, Class II restorations as well as preformed stainless steel crowns in primary molars from the reformatted meta-analysis by Hickel *et al*.[11]

RESULTS

Between January 1, 2002 and December 31, 2008, 1231 Class II Vitremer restorations were placed. Of these restorations, 427 restorations met the criteria for inclusion in the study. The restorations were almost equally divided between the maxillary (48.7%) and mandibular (51.3%) arches, with the most commonly restored tooth being the mandibular first primary molar (34%). (Table 1)

Only 11 failures were noted resulting in a 3-year success rate of 97.42%. Twenty-seven percent (27%) of failures occurred in the maxillary arch, seventy-three percent (73%) in the mandibular arch. Fifty-five percent (55%) of all failures occurred in the mandibular first molars. First molars represented sixty-four percent (64%) of failures while the second molars represented thirty-six percent (36%). The average age of the patient at the placement of the failed restoration was 5.82 years with a range from 2.71 to 10.90 years. The 11 failures in restorations occurred in 9 children. (Table 2)

The annual failure rate in Hickel's meta-analysis ranged widely for all materials. When applying Burke's methodology to studies on RMGIC the normalized annual failure rate was 5.0% with a range of 0.8% – 10%. The current study fell into the low end of the range. (Table 3)

Although a 3-year survival rate was the barometer of success of this study, some restorations could be followed radiographically for as long as 7 years after placement. Seventy-three restorations were still seen at 4 years, 58 at five years, 21 at six years, and 5 at seven years. There was only one failure noted in these long-term restorations.

Table 1. Breakdown of restorations by tooth and arch

Tooth #	Frequency	Percent	Arch
Maxillary right second primary molar	51	11.9%	
Maxillary right first primary molar	52	12.2%	
Maxillary left first primary molar	56	13.1%	
Maxillary left second primary molar	49	11.5%	
Maxillary	*208*	-------	*48.7%*
Mandibular left second primary molar	34	8.0%	
Mandibular left first primary molar	73	17.1%	
Mandibular right first primary molar	72	16.9%	
Mandibular right second primary molar	40	9.4%	
Mandibular	*219*	-------	*51.3%*
Total	427	100%	*100%*

Table 2. Breakdown of failures by age, tooth and surface.

Tooth	Surface	Age at Placement of Restoration	
Maxillary right second primary molar	MO	5.32	9%
Maxillary left first primary molar	DO	7.15	9%
Maxillary left second primary molar	DO	7.15	9%
Mandibular right first primary molar	DO	2.71	55%
Mandibular right first primary molar	DO	6.67	
Mandibular right first primary molar	DO	5.96	
Mandibular right first primary molar	DO	5.35	
Mandibular right first primary molar	DO	4.92	
Mandibular right first primary molar	DO	2.71	
Mandibular right second primary molar	MO	10.90	18%
Mandibular right second primary molar	DO	5.21	
Average Age		5.82	100%

Table 3. Analysis of studies of survival of Class II restorations from the modified meta-analysis by Hickel et al[11] in primary molars using the Burke[12] methodology

Material	Number of Studies	Range of Numbers of Restorations	Range of Years of Studies	Normalized Annual Failure Rate
Amalgam	13	17-706	2-5	9.2 (0-14.2)
Composite	7	19-105	2-6	5.2 (0-10.3)
Compomer	8	17-159	2-3	5.5 (0-11)
SSC	13	18-673	2-9	3.9 (0-14)
RMGIC	7	19-406	2.5-4	5.0 (.8-10)
RMGIC-Webman et al	1	426	3	0.86

DISCUSSION

Replacement of restorations that have failed or otherwise outlived their usefulness is a major part of a dental practice. Replacements generally lead to what has been described as a "death spiral" of events including an increase in size of the restoration, endodontic complication, pain and infection as well as tooth and space loss. Decreasing the failure rate of restorations can lessen morbidity and expense. For these reasons it is imperative that we understand the survival rates of restorative materials.[13]

Throughout the course of this study only eleven failures were found for a success rate of 97.42%. It is important to note that the 11 failures occurred in only 9 children. Although this study did not control for patient behavior, bruxism, fluoride exposure, the size of the restoration and oral hygiene, all of these variables could be factors in the failure of restorations. The most common site of restoration placement, as well as the most common site of failure (55%), was the mandibular first primary molar. This could be attributable to the unique anatomy of this tooth, a narrow buccolingual width and relatively large pulp chamber. There was a wide range of ages for when the few restorations that failed were placed, therefore no conclusion can be drawn from the relationship between age of placement and failure in this study.

The success of Vitremer was previously discussed in a similar study by Croll *et al* [10] In both this study and Croll [10] all restorations were placed by one dentist. However, slight differences in techniques and conditions, may have led to the different outcomes. Croll's[10] annual failure rate for Class II restorations was 2.2 percent versus 0.86 percent for the current study. In comparing the studies the following differences were noted:

1. Croll[10] limited his restorations to smaller cavities which lent themselves to ideal Class II preparations and used preparations analogous to amalgam. Although large and small sizes of restorations were done using Vitremer, in this study, the slot design of preparation was used. This technique eliminated the isthmus portion of the restoration, the weakest area.
2. In this study, the primer was applied, thoroughly dried but not polymerized. Although, initially the primer was applied and polymerized as per the manufacturer's instructions, in some restorations a space between the material and the preparation could be seen on radiographs. Once the practice of thoroughly drying the primer and not polymerizering it was used this space was not seen under restorations. More research may be necessary to determine if this truly has an effect on success.
3. In this study the restorations were sealed. Croll[10] abandoned this practice after a few years.

4. This study took place in the fluoridated community of South Miami, Florida, while the Croll *et al* [10] study took place in the non-fluoridated community of Doylestown, Pennsylvania.
5. Croll´s[10] study used clinical examination while this study used only radiographic evidence and chart review.

In addition to not polymerizing the primer, in the present study Vitremer was used in slight variance to the manufacturer's instructions in two other ways. Although the rationale for these changes were mostly anecdotal, there are few studies showing improvement or diminishment of the material's properties using these techniques.[10, 14] Firstly, similar to Croll *et al*[14], in this study, an alcohol wetted gloved finger was utilized to compress and smooth the restoration. In addition, rather than using the gloss that is supplied with the Vitremer kit, the tooth was sealed with conventional sealant. This technique seals occlusal pits and fissures not involved in the restoration. It produces a smooth surface and protects the restoration during the setting process. Croll abandoned this technique during his study. [10]

Success and failure of restorations will vary according to what is being measured and the methodology used. Roberts *et al*[15], Croll *et al*[10] and others, analyzed variables such as marginal adaptation, axial contour, occlusal volume, and change of color to assess longevity of restorations. These studies required visual clinical examination of every restoration. The present study had a more practical approach to define success. A restoration was successful if it performed adequately for 3 years and did not require replacement or extraction. Using these practical criteria, which are used typically in a private practice, this retrospective study may have resulted in a higher success rate than seen in studies using more demanding technical criteria. Having only one dentist (MW) perform the restorations and evaluate the need for replacement may introduce some bias in the study but it also adds to the consistency of the procedure and eliminates operator variability.

Pediatric dentists are challenged to provide ideal care while meeting parent's expectations. While in many practices tooth-colored materials are used only for minimal restorations, in the clinical practice where the current study was conducted that was not the case. The demand for esthetic restorations was so great that Vitremer was used as almost the only restorative material for primary molars. It was used in hypoplastic teeth, in cavities with divergent axial walls and in other situations where preformed stainless steel crowns would be traditionally employed. Without these larger restorations the success rate could have been higher.

Hickel's meta-analysis provided a convenient gauge to compare this study with survival rates of various materials. However, two pitfalls may exist in using this analysis. First, one cannot account for all variables that may influence survival of restorative materials such as operator's skills as well as variables related to the patients including behavior, caries rate, fluoride exposure, oral hygiene, etc. Secondly, the annual failure rate assumes that equal numbers of restorations fail each year of the study. There is some evidence from this study that failures tend to occur early in the life of a restoration. In the group of restorations seen at 4, 5, 6, and 7 years after placement only one failure was seen.

Burke *et al* [12] developed a formula to analyze multiple studies of longevity of restorative materials which results in a number that represents the survival rate of that particular material. They termed this novel approach: the "normalized failure index". As Burke proposed this index to evaluate the longevity of materials in permanent teeth, his inclusion criteria was for a minimum study duration of 3 years. Because expectations of survival for primary teeth are shorter and the scarcity of longevity studies in primary teeth, a change in this criterion for acceptable studies was made from 3 years to 2 years duration. It appears that this study has had extraordinary results when the comparison is made to the normalized failure rate for various materials. However, one should note that the range of success for restorations in every material category is extremely large. How one measures longevity, the conditions of the study, the number of restorations as well as the length of the study make a great deal of difference in the results. In an analysis of studies of tooth-colored proximal restorations in primary teeth Toh and Messer[16] concluded that RMGIC materials had the highest success rate for the entire range of tooth-colored materials. They further suggested that prospective longevity studies in the primary dentition should be at least 5 years to be valid.

In 2010, Killian and Croll[17] showed that another RMGIC had similar usefulness as Vitremer. Ketac Nano, a "nano-ionomer" RMGIC (3M ESPE) manufactured using nano- technology, was introduced in 2007. However, to date, there are no studies documenting its clinical durability and reliability. All RMGIC's are not the same; their handling characteristics[14] and survival times may differ substantially from one another[11]. This is true of the success of every brand of material within a particular class (composite, compomer, glass-ionomer and RMGIC) and points to the limitations in comparing the success of classes of materials rather than brands of materials. As the demand for tooth-colored restorations increases, with their unique exacting techniques it is important to be able to evaluate individual materials as well as methods of using each of them. Attention to detail and adherence to planned technique is the hallmark of a successful restoration as well as a successful practice but success in the hands of one dentist does not entirely predict the success in every practice.

Some of the limitations of this study include the design of the study, the number of restorations that did not meet the inclusion criteria and the demographics of this patient population. As a retrospective study, the patients were not specifically followed after they were identified as having a qualifying restoration and no particular effort was made to recall these patients as might have occurred with a prospective study. Furthermore, the practice followed the guidelines for radiographic exposure of the American Academy of Pediatric Dentistry. Therefore, no special effort was made to assess the teeth with these restorations by taking radiographs more frequently than prescribed by the guidelines. The practice is in a very mobile community where many of the children come from South and Central America as well as the Caribbean. The mobility of the area, the long distance that some patients travel and normal attrition of patients, account for much of the lack of follow-up. Finally, this practice serves a high-income, well-educated population with a relatively low caries rate. The results of this study may not be applicable to all populations.

CONCLUSION

Under the conditions presented, the Vitremer RMGIC Class II restorations performed well compared to other restorative materials as analyzed utilizing Burke´s novel approach of normalized failure rates.

ACKNOWLEDGEMENTS

The authors wish to thank Dr. Theodore "Ted" Croll for his valuable input and guidance.

REFERENCES

1. Qvist, V, Laurberg, L, Paulsen, A, Teglers, PT. Class II restorations in primary teeth: 7-year study on three resin-modified glass ionomer cements and a compomer. Eur J Oral Sci;112:188-196. 2004
2. Hubel, S, Mejare, I. Conventional versus resin-modified glass-iomomer cement cement for Class II restorations in primary molars. A 3-year clinical study. Int J Peadiatr Dent;13:2-8. 2003.
3. Folkesson, U, Andersson-Wenclert, I, Van Duken, J. Resin-modified glass ionomer cement restorations in primary molars. Swed Dent J ;23:1-9. 1999.
4. McLean JW, Wilson AD. The clinical development of the glass ionomer cements, formulations and properties. Aust Dent J; 22:31-6.1977
5. Croll, TP, Berg, JH, Resin-modified glass-iomomer cement restoration of primary molars with proximating class II caries lesions. Compendium; 28(7);372-377. 2007.
6. Donly, KJ, Nelson, JJ, Fluoride release of restorative materials exposed to fluoride dentifrice. J Dent Child: July-Aug;240-241. 1997.
7. Garcia-Godoy, F, Jensen, ME. Artificial recurrent caries in glass ionomer lined amalgam restorations. Am J Dent; 1990;3:89-93.
8. Rawls, HR. Evaluation of fluoride-releasing dental materials by means of in vitro and in vivo demineralization models: reaction paper. Adv Dent Res 1995;9:324-331.
9. Donly, KJ. Enamel and dentin demineralization inhibition of fluoride-releasing materials. Am J Dent;7:275-278. 1994.
10. Croll, TP, Bar-Zion, Y, Segura, A, Donly, KJ. Clinical performance of resin-modified glass ionomer cement restorations in primary teeth, a retrospective evaluation. JADA;132:1110-1115. 2001.
11. Hickel, R, Kaaden, C, Paschos, E, Buerkle,V, Garcia-Godoy, F, Manhart, J. Longevity of occlusally-stressed restorations in posterior primary teeth. Am J Dent;18(3):198-211. 2005.
12. Burke, FJT, Singh, V, Wilson, NHF. The Normalized Failure Index: A method for summarizing the results of studies on restoration longevity? Oper Dent;38:488-496. 2013.
13. Quist, V, Laurberg, L, Poulsen, A, Teglers, PT. Longevity and cariostatic effects of everyday conventional glass-ionomer and amalgam restorations in primary teeth: Three-year results. J Dent Res;76(7):1387-1396. 1997.
14. Croll, TP, Killian, CM. Class I and Class II light-hardened glass-ionomer/resin restorations. Compendium;14:908,910-912,914. 1993.
15. Roberts, JF, Attari N, Sherriff, M. The survival of resin modified glass ionomer and stainless steel crown restorations in primary molars, placed in a specialist paediatric dental practice. Br Dent J; 198(7): 427-431. 2005.
16. Toh, SL, Messer, BM. Evidence-based assessment of tooth-colored restorations in proximal lesions of primary molars. Pediatr Dent;29(1):8-15. 2007.
17. Killian, CM, Croll, TP. Nano-ionomer tooth repair in pediatric dentistry. Pediatr Dent;32(7):530-535. 2010.