Clinical Evaluation of Restorative Materials in Primary Teeth Class II Lesions

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Objective: *The aim of this study was to evaluate clinical success of primary teeth class II lesions restored with different restorative materials [Hybrid Composite Resin (HCR), Resin Modified Glass Ionomer Cement (RMGIC), compomer, and Giomer Composite Resin (GCR)] followed up for 24 months.* ***Study Design:*** *This study was carried out on 146 primary molars of 41 children in the age range of 5-7 years. The class II lesions in primary molars of a patient were restored using different restorative materials. Restorations were evaluated according to FDI-criteria and their survival rates were determined. Data were analysed with Pearson chi-square, Kaplan-Meier and Wilcoxon (Breslow) tests (α = 0.05).* ***Results:*** *The failure rates of restorative materials were as follows: compomer 33.3%, RMGIC 28.1%, HCR 22.5% and GCR 21.1%.* ***Conclusions:*** *While the functional failure was the most important factor in restorative material failure, RMGIC was the most successful material in terms of biological evaluation criterion and GCR had the longest survival rate.*

Key words: primary teeth, dental restoration failure, prospective study

INTRODUCTION

Because of their contribution to mastication and their space maintainer function until being replaced by permanent premolars, primary molars should be kept healthy in the mouth until they fall out. Adhesive materials such as Hybrid Composite Resin (HCR), Resin Modified Glass Ionomer Cement (RMGIC) and Glass Ionomer Cement (GIC) have been used for many years in primary teeth.[1,2]

Factors such as fracture resistance, fatigue resistance, degradation, erosion resistance, bonding strength, polymerisation shrinkage, post-operative sensitivity, biological compatibility, technical accuracy and anti-cariogenic effects are significant in the clinical success of restorative materials.[3]

HCR is recommended in the low caries risk group patients, compomer in the moderate caries risk group patients, and GIC with high fluoride content in the high caries risk group patients.[4] Furthermore, along with the developments in fluoride releasing materials, giomer restorative materials are available.[5] Total and free fluoride release from giomer was found to be higher than compomer and lower than RMGIC.[6-8]

Evaluation of the restorative materials in primary teeth has been mainly carried out as material comparisons.[9-12] Recently developed Giomer Composite Resin (GCR) can be used as an alternative restorative material in primary teeth due to its fluoride release properties.[13] Although there are little data about the usage of giomer in permanent dentition, there is no data about its usage in primary teeth in related literature.

The aim of this study is to evaluate the clinical success of primary teeth class II lesions restored with different restorative materials (HCR, RMGIC, compomer, and GCR) followed up for 24 months with three-month clinical and six-month radiographical evaluation periods.

MATERIALS AND METHOD

The present study is prospective, non-blinded, parallel-group one with a balanced randomized block design, conducted in Turkey. The study had been approved by Ataturk University Health Sciences Institute Ethics Committee (2006.3,1/26). Before the treatment, children and their parents were informed about procedures and consent letters about treatment and radiographical examination were received.

Children with a behaviour rating of 3 or 4 on the Frankl scale were included in the study (Frankl 3: The child is cooperative, but somewhat reluctant/shy. Frankl 4: The child is completely cooperative and also enjoys the experience).[14] Inclusion criteria for radiography were having radiolucency in the outer half of the dentin, normal view of the lamina dura and periodontal space, and permanent teeth germ below the primary teeth in normal position.

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Patients with any systemic disease, known or suspected allergy to any drug or restorative material, history of bruxism, teeth clenching and skeletal and dental malocclusions, and also teeth with discolouration and developmental defects or needing endodontic treatment or extraction were excluded from the study.

This study was carried out on 41 children with a high caries risk who were admitted to the clinic of Pedodontics Department, Faculty of Dentistry at Ataturk University, Erzurum, Turkey. Besides gathering informed consents, pre-treatment examination and randomisation steps of the study were performed by main investigator (FS).

Patients' teeth were randomly classified in four restorative material groups [HCR (Valux Plus, 3M Dental Products, St. Paul, MN, USA), RMGIC (GC Fuji II LC, GC Corporation Tokyo, Japan), compomer (Dyract AP, Dentsply/De Trey, Konstanz, Germany), and GCR (Beautiful, Shofu Inc, Kyoto, Japan)]. A2 colour was selected as the standard for restorative materials.

For every patient, similar lesions were chosen to place the restorative materials. Conservative mesio-occlusal and disto-occlusal cavities which are similar to the class II cavity dimensions indicated in the study of Suwatviroj et al were prepared with a high-speed diamond round bur (no. 010, SSWhite Burs Inc, Lakewood, NJ) and water coolant by a single operator (FS).[15] Local anaesthetic (Ultracain-DS, Hoechst Marion Roussel, Turkey) was used in children who experienced pain during carious dentin removal. Carious dentin removal was evaluated according to clinical criteria of Kidd et al (dental explorer should not stick in the dentine, it should not give a tug-back sensation and the cavity must be stain-free).[16] Cavo-surface angles were not bevelled and no retentive grooves were placed.

Rubber dam isolation and suction were used for moisture control after cavity preparation. A wedge and metal matrix band (Quickmat, Polydentia SA, Mezzovico, Switzerland) was placed interproximally. Restorative materials were applied according to the manufacturer's directions (Table 1) by a single practitioner (FS). The restorative materials were polymerized with a quartz-tungsten halogen light-curing unit (Hilux Ultra Plus, Benlioglu Dental Inc., Ankara, Turkey). The intensity of the light exceeded 800 mW/cm^2. After polymerization, finishing was accomplished with aluminium oxide discs of decreasing abrasiveness (Sof-Lex XT, 3M ESPE, Seefeld, Germany).

After 24 months follow-up period, including three-month clinical and six-month radiographical evaluation periods, the restorations were evaluated according to FDI-criteria.[17] FDI criteria set a different background for the evaluation of dental restorations by introducing three groups of criteria: esthetic, functional and biological. Each of these groups has sub-groups with 16 evaluation criteria in total (Graph 2). For all three groups, five steps of grading are used for evaluation (1-Clinically excellent/very good, 2-Clinically good, 3-Clinically sufficient/satisfactory, 4-Clinically unsatisfactory, 5-Clinically poor). All evaluations were carried out by a specialist researcher (TG) and visual evaluations were done on digitally stored images.

Scores of 4 or 5 were considered as failure. Teeth showing periapical problem radiographically within three months after restoration placement were excluded from the study. If there was a failure during control periods, follow up of restorative materials was terminated. But, if the tooth shed during the follow up, it was considered to be successful.

Statistical Package for the Social Sciences for Windows (SPSS version 21.0, Chicago, IL, USA) was used for the statistical analysis in the 5% significance level. Kappa analysis was used for intra-examiner reproducibility and Pearson chi-square analysis for demonstrating the difference between restorative material distributions according to the clinical evaluation criteria. The survival analysis was performed using the Kaplan-Meier and Wilcoxon (Breslow) methods. When a significant difference among the mean follow-up time of restorative materials was found, chi-square analysis was used to recognize material or materials responsible for the present difference.

Table 1. Materials, batch numbers, compositions, and instructions for use

Material	Composition	Instructions for Use
Beautiful, Lot 30502	Bis-GMA, TEGDMA, S-PRG filler, inorganic glass filler, aluminuoxide, silica, DL-camphorquinone	-20s cure
Dyract AP, Lot 0203001191	UDMA, TCB resin, strontium-fluoro-silicate glass, strontium fluoride, photo initiators, stabilizers	-40s cure
GC Cavity Conditioner, Lot 402261	20% polyacrylic acid, 3% $AlCl_3$	-10s apply -Gently wash and dry
GC Fuji II LC, Lot 707171	Powder: Aluminosilicate glass. Liquid: Polyacrylic acid, HEMA, 2,2,4,trimethyl hexamethylene dicarbonate, TEGDMA	-Activate capsule and mix for 10s -Syringe into the cavity -Light cure for 20s
Prime&Bond NT, Lot 0507000014	PENTA, UDMA, di-and trimethacrylate resins, nanofillers, photo initiators, stabilizers, cetylamine hydrofluoride, acetone	- 20s apply - Gently air dry for 5s - Light cure for 10s
Valux Plus, Lot 5540SB	BisGMA, TEGDMA, camphorquinone, inorganic filler zirconia-silica	- Apply in increments of 2mm thickness - Cure for 40 sec/increment
Vococid Etching Gel, Lot 1063	35% phosphoric acid	- Etch enamel 20-30s, dentin 15s - Rinse and air dry

Abbreviations: BisGMA, bisphenol A-glycidyl methacrylate; TEGDMA, triethyleneglycol dimetacrylate; S-PRG, surface prereacted class-ionomer; HEMA, 2-hydroxyethyl methacrylate; UDMA, urethane dimethacrylate; TCB resin, tetracarboxylic acid hydroxyethyl methacrylate ester; PENTA, dipentaerythritol penta acrylate monophosphate

RESULTS

In this study 146 primary molar class II lesions (73 primary first molar, 73 primary second molar) in 41 children (19 boys and 22 girls) with an age range of 5-7 years, were restored. All patients attended the recalls (dropout rate: 0%). For each material the mean age of the children is presented in Table 2. Distribution of the age, gender, jaw, tooth type and restorative material are presented in Table 3.

Kappa values of intra-examiner agreement for determining the clinical and radiographical selection criteria of the teeth before restorative material application and for determining clinical and radiographical success at control visits are 0.91 and 0.86, respectively.

During the study period, restorative materials in one teeth of a patient, exfoliated in the 12th month, was recorded as successful.

According to the evaluation factors in Table 3, there were not any statistically significant differences among the given groups ($p>0.05$).

Distribution of the failure percentage of general, aesthetic, functional and biological evaluation resulting in time dependent control periods of restorative materials is presented in Graph 1. Maximum failure of compomer was observed in the 6th and 24th month, and in the 12th month for RMGIC. A homogeneous distribution of time-dependent failure was detected for HCR and GCR.

Distribution of restorative material failure rate over the clinical evaluation criteria is presented in Graph 2. The failure rate was

Table 2. Patient mean age (year) and failures (%) seen in control periods of restorative materials

Material	Mean Age ±SD	Failure Period (month)								
		3	6	9	12	15	18	21	24	Total [% (n)]
HCR	6.3±0.8[c]	2.5	2.5	5	5	2.5	0	0	5	22.5 (9)
RMGIC	6.0±0.5[b,c]	3.1	0	0	12.5	0	6.3	6.3	0	28.1 (9)
Compomer	5.3±0.5[a]	5.6	11.1	5.6	0	0	0	0	11.1	33.3 (12)
GCR	5.8±0.9[b]	0	7.9	0	2.6	0	5.3	5.3	0	21.1 (8)
Total	5.9±0.8	2.7	5.5	2.7	4.8	0.7	2.7	2.7	4.1	26 (38)

There is not any statistical difference between the same letters ($p<0.05$).

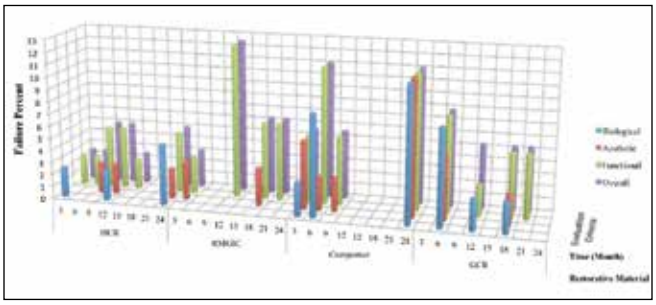
Table 3. χ^2 results and distribution of the clinical criteria results over age, gender, jaw, tooth type, and restorative material factors

	Factors	Result criteria (%)					
		C	S	F	D	Total [% (n)]	P
Age	5	71.9	0	28.1	0	100 (57)	
	6	73.6	0	26.4	0	100 (53)	0.496
	7	75	2.8	22.2	0	100 (36)	
	Total	73.3	0.7	26	0	100 (146)	
Gender	Male	68.5	0	31.5	0	100 (73)	0.208
	Female	78.1	1.4	20.5	0	100 (73)	
	Total	73.3	0.7	26	0	100 (146)	
Jaw	Maxillary	72.2	1.4	26.4	0	100 (72)	0.59
	Mandibular	74.3	0	25.7	0	100 (74)	
	Total	73.3	0.7	26	0	100 (146)	
Tooth Type	Maxillary IV	69.7	3	27.3	0	100 (33)	
	Maxillary V	74.4	0	25.6	0	100 (39)	0.28
	Mandibular IV	65	0	35	0	100 (40)	
	Mandibular V	85.3	0	14.7	0	100 (34)	
	Total	73.3	0.7	26	0	100 (146)	
Restorative Material	HCR	77.5	0	22.5	0	100 (40)	
	RMGIC	71.9	0	28.1	0	100 (32)	0.602
	Compomer	66.7	0	33.3	0	100 (36)	
	GCR	76.3	2.6	21.1	0	100 (38)	
	Total	73.3	0.7	26	0	100 (146)	

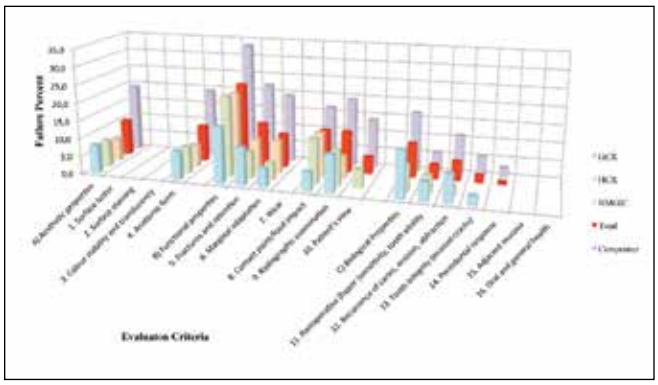
C. Follow-up completion (Censored); **S.** Successful; **F.** Failure; **D.** Drop-outs

33.3% for compomer, while other materials such as RMGIC and HCR demonstrated lower failure rates, respectively. With a failure rate of 21.1%, GCR was proved to be the most successful material (Table 4).

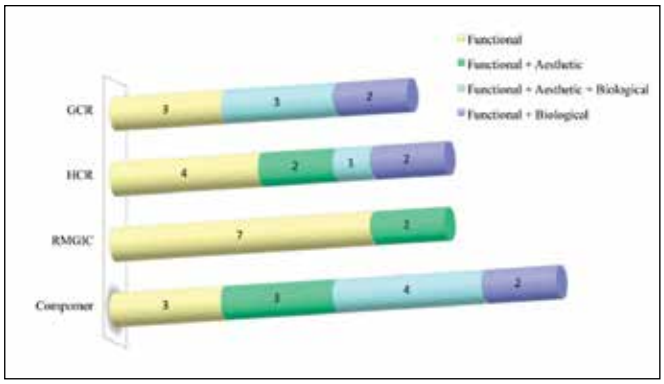
Graph 1 Distribution of failure rate of time-dependent restorative materials over the determined criteria



Graph 2 Distribution of failure percentage of restorative material over the clinical evaluation criteria



Graph 3 Distribution of the observed failure type in restorative materials



Failure rates and amounts of the clinical evaluation criteria of restorative materials are presented in Table 4. By the end of 24 months, 108 of 146 restorations were found to be successful. No statistical significance was found between the restorative materials regarding any of the clinical evaluation criterion ($p>0.05$).

The average time and standard deviation of restorative material failure due to the main evaluation topics are presented in Table 5. There was no statistically significant difference between the average failure times of restorative materials ($p=0.907$). Also, biological failure was not detected for RMGIC.

Failure type distribution of the restorative materials is presented in Graph 3. A total of 26% (n=38) failures in 146 teeth were found. All functional, aesthetic and biological failures were found to be 5.5% (n=8), totally. A combination of functional and aesthetic failures was observed in 4.8% (n=7), while in 4.1% (n=6) a combination of functional and biological failures was identified. Single functional failure was observed in 11.4% (n=17).

A survival graph of restorative materials according to the Kaplan-Meier analysis is presented in Graph 4. When the restorative material factor was evaluated for compomer, failures were recorded especially in the 6th and 24th months and the survival rate at the end of the 24-month was found as 66.7% (Graph 4). The biggest decline was observed in the 12th month for RMGIC. RMGIC had a survival rate of 71.9% in the 24th month. The highest survival rate (79.9%) was observed in GCR, followed by HCR (77.5%). The mean survival times of restorative materials, ranging from 20 to 21.5 months, are ranked as follows: compomer<RMGIC<HCR<GCR. The survival rate of restorative materials was arranged similar to their mean survival time. No statistical significance was found between the survival rates of the restorative materials (Wilcoxon: $p=0.582$).

DISCUSSION

The progression rate of proximal caries lesions in primary molars is relatively faster than in permanent teeth.[18] Therefore, after restoration preservation of primary teeth in a healthy state is expected until eruption of permanent teeth. Restorative material is the main factor in determining the performance of the restoration of primary teeth.[19,20] HCR, RMGIC, and compomer are widely used materials in restorations in primary teeth.[10,11,21,22] Recently, GCR material has been presented as an actual hybridization of glass ionomer and composite resin with a long-term fluoride release feature.[13,23] We found no literature about the clinical success of GCR in the primary teeth. Our study was designed to compare the clinical success of widely used restorative materials with GCR in primary teeth.

It was reported that if teeth are restored at earlier ages, longevity will be lower.[24] On the contrary, some researchers stated that survival of the restorative material was not affected by the patients' age.[10,25] Even though the difference between mean age values of the materials was not statistically significant in our study, survival rates and average survival times increased in direct proportion with age. Having a similar extent of caries, the older age group of children would indicate low caries activity compared to the young age group. Barr-Agholme reported that although the caries activity of children does not have a significant impact on restoration success, the lower caries risk level may have positively affected the survival of restoration.[10]

Marginal staining results from seepage or leakage of oral fluids between the restoration and tooth structure.[17] Hayashi *et al* reported that marginal deterioration and cavo-surface discoloration may be predictors of future failure for posterior resin composites.[26] Mjör *et al* reported that composite resin, GIC, RMGIC and compomer did not show marginal staining of the primary teeth.[9] In contrast to our results, studies evaluating marginal staining showed that different failure rates up to 50% might result from the difference in the bonding agents used.[27-29] In our study, using one type of bonding agent, successful results have been obtained from the adhesive restorative materials. Also, no colour change was recorded for restorative materials by the end of the 24th month in the present study.

Table 4. Restorative material failure rate (%) over clinical evaluation criteria

	Clinical Evaluation Criteria	Restorative Materials				
		HCR (n=40)	RMGIC (n=32)	Compomer (n=36)	GCR (n=38)	P
Aesthetic	Surface luster	-	-	-	-	
	Surface staining	-	-	-	-	
	Colour stability and translucency	-	-	-	-	
	Anatomic form	7.5	6.3	19.4	7.9	0.22
	Total	7.5	6.3	19.4	7.9	0.22
Functional	Fractures and retention	7.5	9.7	22.2	10.5	0.22
	Marginal adaptation	5	9.7	19.4	5.6	0.135
	Contact point (food impact)	12.5	12.5	16.7	5.3	0.487
	Radiographic examination	10	6.3	19.4	10.5	0.364
	Patient's view	5	-	13.9	-	0.162
	Total	22.5	23.3	33.3	16.7	0.417
Biological	(Hyper-)sensitivity, tooth vitality	5	-	5.6	5.3	0.621
	Recurrence of caries	2.5	-	11.1	7.9	0.16
	Tooth integrity	-	-	5.6	2.6	0.288
	Periodontal response	-	-	2.8	-	0.38
	Adjacent mucosa	-	-	-	-	
	Oral and general health	-	-	-	-	
	Total	7.5	0	16.7	13.2	0.101
Overall Total		22.5	28.1	33.3	21.1	0.611

Graph 4 Time-dependent Kaplan-Meier survival curves of the restorative materials

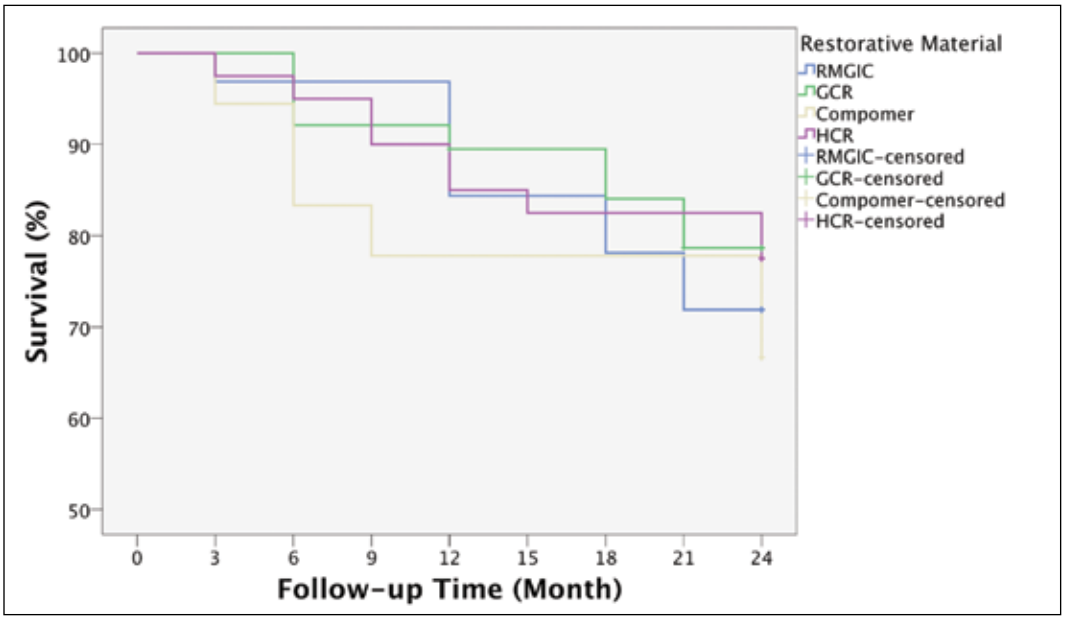


Table 5. Restorative material average failure time (month) and standard deviation over the failure type

	Clinical Evaluation Criteria			
Material	General	Aesthetic	Functional	Biological
HCR	12.7±7.3	15±7.9	12.7±7.3	13±10.5
RMGIC	14.3±5.8	10.5±10.6	14.3±5.8	-
Compomer	12±9	13.3±10.2	12±9	11.5±9.8
GCR	13.5±6.8	10±6.9	13.5±6.8	9.6±5.4
Total	13±7.3	12.6±8.5	13±7.3	11.1±8

One of the main reasons for restoration replacement is secondary caries in permanent teeth and fractures or complete loss in primary teeth.[19,30] Therefore, broken restorations emphasize more clinical care for the preservation of oral health during primary dentition. Also, bruxing patients were not included in this study, because bruxism plays an important role in fatigue development in the tooth-restoration complex.[31,32] According to previous studies a two-year success rate of restorative material fracture and retention evaluation are as follows: 59% for HCR, 98% for RMGIC, 95% for GCR and 69-100% for compomer.[12,20,29,33-35] In our study the determined success rate for compomer (86%) was compatible with the reported findings; HCR (95%) was over these limits, and RMGIC (91%) and GCR (89%) were under these limits. The differences may result from the dissimilarities in the patients mean age and the cavity sizes.

According to the radiographic evaluation results, RMGIC was the best and compomer was the worst material, although there was no statistically significant difference between all materials. Restoration or tooth fracture was the primer reason, while apical pathology was the secondary reason for radiographic failures. Kavvadia *et al* found only one failure of secondary caries in compomer with clinical and radiographical signs over a two-year time period.[29] In this study, like previous findings, radiographic failure was observed in all secondary caries cases.

Microleakage or stresses in the restorative material might result in postoperative sensitivity.[36] Also, postoperative sensitivity may depend on the restorative technique rather than the type of dentin adhesive used.[37] Failure of postoperative sensitivity and tooth vitality was identified in two teeth of each restorative material. Unlike other restorative materials, no postoperative sensitivity was observed in RMGIC, which may be due to the physico-chemical connection of this material to enamel and dentin.

Secondary caries is the other main reason for restoration replacement among primary teeth.[9] In secondary caries the evaluation success rate of the restorative material found in researches are: 59-100% for HCR, 98-100% for RMGIC, 69-100% for compomer, and 100% for GCR.[5,10,12,20,27-29,33,38,39] In our study, the success rates of HCR (97.5%), RMGIC (100%), and GCR (92%) is similar to previous findings. In addition, compomer (89%) had the lowest success rates in secondary caries. Paterson *et al* reported that loss of marginal integrity can result in secondary caries.[40] Secondary caries were observed in 33.3% of the restorations, exhibiting fracture and adhesion failure. Low secondary caries rates were observed in HCR (n=1) and RMGIC (n=0), which is probably because of their high success rate at fractures and retention criterion. Also, low risk of secondary caries in RMGIC may be as a result of the acid-base resistant layer.[41]

The success rates of the clinical evaluation criteria in restorative material groups is as following: GCR>HCR>RMGIC>Compomer. Qvist *et al* reported no difference between the clinical success of three different kinds of RMGIC and compomer at the end of a seven-year observation period.[20] In addition, Hse and Wei found no statistical difference between the clinical success of HCR and compomer.[28] Gordon *et al* reported 100% success after eight-year follow-up for GCR, used in permanent teeth class I and class II cavities.[5] In spite of its lower success rate (79%), GCR was the most successful material in this study.

Papathanssiou *et al*, found the median survival time for composite resin and GIC as 32 and 12 months, respectively, and four-year survival estimate for composite resin and GIC as 40% and 5%, respectively.[42] Success rate of HCR was higher than the RMGIC in 24-month time-period, in accordance with the results of the researchers.

HCR and GCR exhibited better results in clinical assessments. The reason for the success of GCR and HCR is their filler size, which may increase their physical properties.[23] Fluoride releasing property and filler size of GCR may be effective in its overall success.[13,23]

Hickel *et al* reported the reasons for the observed failures between 6-18 months as following: broken tooth or restoration, discolouration of edge or restoration material, fractures and vitality loss.[17] In our study, there was no distinct difference among the materials by the end of 24 months. A 24-month follow-up period may not give detailed information about the clinical success of restorative materials; therefore longer-term follow-up studies may be more enlightening.

In this study it was found out that the most important factor in restorative material failure is the functional failure. All restorative materials were found to be successful in primary molar class II lesions over 24-month period. Further follow-up is needed to evaluate the long-term success rates of the restorative materials.

CONCLUSION

In conclusion, based on the findings of our studies resin restorative materials have been shown to perform favourably in primary molar class II cavities. As a result of 24 months clinical assessments, failures appeared mostly in functional, aesthetic and biological criteria, respectively.

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