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ORIGINAL SCIENTIFIC ARTICLE

Comparison of resin modified glass ionomer cement and composite resin in class II primary molar restorations: a 2-year parallel randomised clinical trial

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Abstract

Aim To compare the 2-year success rates of a Resin Modified Glass Ionomer Cement (RMGIC) with a composite resin in class II primary molar restorations.

Methods Healthy, cooperative children aged 4–7.5 years with at least one carious primary molar requiring a class II restoration were included in this parallel randomised trial and allocated on a 1:1 basis to composite resin (Z250, 3M ESPE) or RMGIC (Vitremer, 3M ESPE). Restorations were assessed semiannually up to 2 years clinically and radiographically using modified United States Public Health Service criteria, with the primary outcome being all-cause failure. Data were analysed per protocol by binomial linear regression with Relative Risks (RR) and their 95% confidence intervals (CI).

Results 55 patients were randomly allocated to either group and 44 analysed at 2 years; with 49 teeth in the Z250 and 55 teeth in the Vitremer group. The all-cause failure rate for both materials was 3% after 1 year (4 and 2% for Z250 and Vitremer, respectively) and 16% after 2 years (16% for both Z250 and Vitremer). Overall, no difference between materials could be found at 2 years (RR = 1.4; 95% CI 0.8, 2.4; P = 0.30). However, Vitremer was associated with more favourable gingival health compared to composite (RR = 0.2; 95% CI 0.1, 0.9; P = 0.03), but also occlusal wear, which was observed exclusively for Vitremer.

Conclusion No significant difference was found in the overall performance of the two materials, making them suitable for class II primary molar restorations, although RMGIC presented more pronounced occlusal wear of limited clinical importance after 2 years.

Keywords Resin modified glass ionomer · Composite resin · Restorations · Primary molar · Randomised clinical trial

Introduction

In addition to amalgam, which has traditionally been used to restore primary molars for over 150 years and is still widely used, other materials e.g. composite resin, glass ionomer cements, and compomers have been gradually introduced in clinical practice. The reasons for the continuing development and increased use of these materials in primary molar teeth include among others: allegations concerning the toxic side-effects of amalgam to the patients and the ecosystem (Eley 1997), a growing demand for aesthetically pleasing restorations, and the recent tendency for a minimal intervention restorative approach (Hickel 1996). The selection of the best restorative material for posterior primary teeth remains a challenge for the clinician, as factors like the extent of the carious lesion, patient age, and patient cooperativeness (Mjör et al. 2002) have to be taken into account.

Composite resin restorations were first used for the restoration of carious lesions more than 50 years ago. As a material that fulfils aesthetic expectations, composites have become increasingly used instead of amalgam (Opdam et al. 2010) and remain a popular primary molar restorative

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material. Composite resin can be successfully used for primary molar Class I restorations (Hickel et al. 2005; Soncini et al. 2007), while a randomised controlled trial has also shown success of Class II composite restorations in primary teeth over a 2-year period (Fuks et al. 2000). Despite the fact that composites shows a similar success rate to amalgam in the short term, their success rate seems to decline in the long term. Loss of retention, marginal discolouration, and secondary caries are considered as the main reasons for failure in composite resin restorations, with these being attributed mainly to polymerisation shrinkage (Fuks et al. 2000). Additionally, composite resin is considered to be a technique-sensitive material requiring a precise placement protocol with extended duration and its success may be compromised when tooth isolation or patient cooperation cannot be successfully achieved (Antony et al. 2008).

Glass ionomer cements were introduced in the early 1970s (Wilson and Kent 1972) and present a number of potential advantages such as fluoride (F) release, chemical bonding to the tooth structure, and favourable biocompatibility. Despite their low fracture toughness and poor wear resistance (Hickel and Manhart 1999), glass ionomer cements are regarded by some researchers as the restorative material of choice in the primary dentition (Milsom et al. 2002; Mjör et al. 2002). The addition of resin components greatly decreased setting time by utilising light polymerisation and improved the handling characteristics of glass ionomer cements, as well as the material's wear resistance and fracture toughness. Thus resin-modified glass ionomer cements (RMGIC) were introduced into general use in the early 1990s. The major advantages of glass ionomer cements, such as fluoride release, biocompatibility, and convenient thermal expansion or contraction properties, as well as physic-chemical bonding to tooth structure were retained (De Gee et al. 1996), resulting in a material far superior to conventional glass ionomer cements, with decreased moisture sensitivity compared to resins (Hübel and Mejàre 2003). Nicholson and Croll (1997) propagated that RMGIC could become a mainstream restorative material for paediatric dentistry, due to its promising clinical properties. However, clinical decision making must be based on critical appraisal of robust evidence from randomised clinical trials or systematic reviews thereof. There exists a single randomised trial (Sengul and Gurbuz 2015) that allocated 41 patients in need of Class II restorations in primary teeth to four different restorative materials and found no difference in failure rate between hybrid composite and RMGIC (Sengul and Gurbuz 2015). This trial however included a limited sample of about 10 patients per restorative material group, which might have influenced its results. Therefore, the aim of the present randomised trial was to compare the in vivo success rate of RMGIC and composite resin used in children for Class II primary molar restorations over a period of 2 years.

Materials and methods

Trial design and participants

This was a two-group single-centre randomised clinical trial with parallel patient allocation to the composite resin and RMGIC groups. Healthy (ASA I, II) and co-operative (Frankl 3, 4) 4.0–7.5 year-old mostly Caucasian children with at least one first or second primary molar requiring a class II restoration were eligible to be included in the trial. All children were patients at the post-graduate clinic in the Department of Paediatric Dentistry, Dental School, Aristotle University of Thessaloniki, Greece. The study protocol was approved by the School's Research Ethics Committee (179/12-4-2012). Informed consent was obtained from the parent or guardian of the child participants included in the study before treatment. Children were randomly allocated to receive either composite resin (Z250, 3M ESPE Dental Products Co. St. Paul, MN) or RMGIC (Vitremer, 3M ESPE Dental Products Co. St. Paul, MN) restorations. The carious lesions should not have invaded the inner third of the dentine, as shown radiographically, and any teeth requiring multi-surface restorations were excluded.

Intervention: restorative technique

Restorations were placed by six trained and calibrated operators who were all 2nd or 3rd year postgraduate Paediatric Dentistry students. These operators had already been trained during their first year of postgraduate studies and were further trained for appropriate cavity shape and sizes on natural extracted primary molars. They were then evaluated by performing 10 class II restorations on appropriate clinic patients prior to initiation of the study.

All the restorations were placed under local analgesia and rubber-dam isolation. Cavities were prepared with a small cylindrical high-speed diamond bur, while soft carious dentine was removed with the use of a round, size 4, low-speed steel burs. A thin, 5 mm width, steel matrix band was secured around the approximal surface with a wooden wedge suitable for primary molar restorations. Both Z250 and Vitremer were used in accordance with the manufacturer's instructions.

Restorations with Z250 After etching the enamel with 37% phosphoric acid gel for 30 s, and the dentine for about 8 s, thorough rinsing and careful drying for 15 s were carried out, ensuring not to overly dehydrate the dentine. A bonding agent (Adper Scotchbond XT, 3M ESPE, St.Paul, MN, USA) was then applied and light-cured for 10 s. The Z250 was incrementally applied in two stages, with each layer

being light-cured for 20 s. The trimming and polishing of the restorations was performed with a conical Arkansas stone. After rubber-dam removal, the occlusion was checked and trimming was repeated if necessary.

Restorations with Vitremer Following cavity preparation, the primer was applied for 30 s and light-cured for 10 s. The Vitremer powder and liquid dose was manually mixed, placed in the cavity with the recommended application tip and light-cured for 40 s. The restoration was then trimmed and polished as above. A finishing gloss was applied using a microbrush, gently blown and cured for 20 s. The occlusion was checked as above.

Outcomes: assessment of restorations

The primary outcome of this randomised trial was failure of the restoration, for any reason. The clinical assessment of the restorations was made at baseline and semi-annually, whereas the radiographic assessment was performed annually. All restorations were assessed by four experienced paediatric dentists and instructors in the Paediatric Dentirstry Clinic that were not involved in restoration placement and had been previously calibrated (Kendall's $W = 0.70$ and 0.88). Accordance of these four assessors had been previously reached by discussing evaluation of 10 primary molar restorations until agreement was obtained. Subsequently, all assessors separately evaluated old class II restorations in 10 clinic patients.

All restorations were evaluated using a modification of the United States Public Health Service (USPHS) criteria (Cvar and Ryge 1971) covering: presence of the restoration, marginal integrity, proximal contacts, anatomical form (including occlusal wear), gingival health, and the presence of secondary caries, with criteria individually judged as A (Alpha), B (Bravo) or C (Charlie) (see Appendix in ESM). Any restoration graded as C by the examiners was considered as unacceptable and had to be replaced. The primary outcome of the trial was all-cause failure of the restoration (i.e. C for at least one criterion), while secondary outcomes included failure of each separate USPHS criterion.

Sample size

Sample size calculation was conducted *a priori* using the following assumptions: alpha of 5%, beta of 20%, baseline failure rate for the composite resin of 15%, minimally important difference in the failure rate between materials of 25% (Casagrande et al. 2013), and use of a Chi square test. A total of 98 teeth (49 per group) was calculated to be required, which, after considering a median 2 primary molars treated per patient, resulted in the total requirement of 50 patients for this trial (25 patients in each group), which was rounded up to 55 patients to account for possible drop-outs.

Randomisation/allocation concealment

An unrestricted computer-generated list of random numbers was used to assign by central allocation through the clinic management patients to the two restoration materials. Each clinician was informed prior to placement of the restoration by a third person to which material was the patient allocated, and all Class II cavities of the patient's primary teeth were restored with the same material.

Blinding

Blinding of the six treatment providers was not possible, as the two materials differ both visually and in protocol. No measures to blind the patients were undertaken, but they were not informed about which material they received and both materials would seem visually similar to laypersons. The four outcome assessors were not told which material had a patient received, but they could probably perceive group allocation, due to their clinical expertise. After data collection a coded dataset with "group 1" and "group 2" as designations for the two materials was prepared and handed to the data analyst, who performed blindly the statistical analysis. The code was broken after finalising the analysis plan and exporting all results.

Statistical methods

Descriptive statistics were calculated as frequencies for all USPHS criteria and time-to-event (failure) for each restoration. Crude differences between the USPHS criteria assessment of the two groups were initially checked with Fisher exact tests. Afterwards, differences in the performance of restorations for each USPHS criterion separately and as overall all-cause failure (failure of at least one USPHS criterion) were assessed with generalised linear regression modelling for the binary family. In this, bivariable analyses for each outcome were fitted, taking into account the clustering of multiple restorations within a patient with robust standard errors, while reporting Relative Risks (RR) and the corresponding 95% Confidence Intervals (CI). Failure here was defined as category B or C for all criteria. Additionally, the potentially significant confounding effects from the factors patient gender, age, tooth type, and jaw were controlled for by calculating adjusted RRs from multivariable models, following a pre-defined protocol (Weinberg 2013). Each confounder was inserted in a separate bivariable model for each outcome and confounders with $P < 0.2$ in this model, were included in a multivariable model with the randomised material. All analyses were run blindly per protocol in Stata

SE 14.0 (Stata Corp, College Station, TX) with a two-sided $P \leq 0.05$. No ancillary analyses for this trial were planned or performed.

Results

Recruitment, participant flow, and baseline data

A total of 65 patients were screened for eligibility in the Paediatric Dentistry Clinic between May 2012-May 2014. 55 children met the inclusion criteria and were randomly allocated to receive either composite resin (Z250) or RMGIC (Vitremer) restorations (Fig. 1). However, 7 patients (5 and 2 in the Z250 and Vitremer group, respectively) didn't show up for the placement appointment, so 48 patients (23 and 25 in the Z250 and Vitremer group, respectively) received the allocated restorations. A total of 113 (60 first and 52 second) primary molars were evaluated at the 12-month follow-up, while a total of 104 (58 first and 51 second) primary molars were evaluated at the 24-month follow-up. There were eight drop-outs for the Z250 group and two drop-outs for the Vitremer group at the 6-month follow-up. Another two restorations were not available for evaluation at the 12-month follow-up for the Vitremer group. Finally, 44 patients were followed up for 2 years, with 49 teeth in the Z250 and 55 teeth in the Vitremer group.

55 children (31 girls and 24 boys) met the inclusion criteria and were randomly allocated to receive either composite resin (Z250) or RMGIC (Vitremer) restorations (Table 1). The mean age of the children was 80.5 ± 15.3 months for the composite resin group and 81.0 ± 16.0 months for the RMGIC group (Table 1). In all, 124 Class II restorations were placed, 61 with Z250 and 63 with Vitremer. One

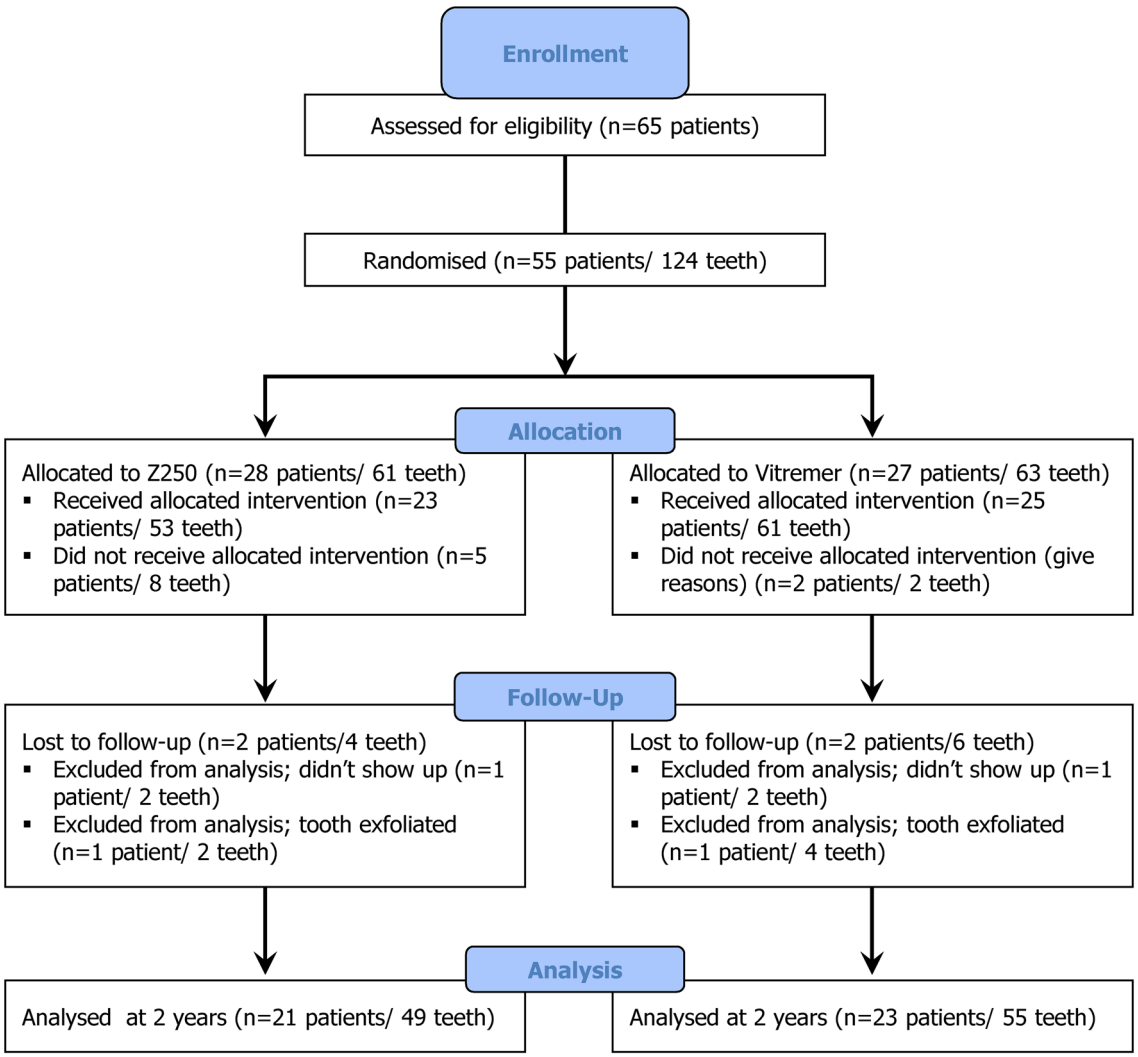

Fig. 1 Flow diagram for the identification, randomisation, and analysis of patients in the trial

Table 1 Demographic characteristics of randomised patients

	Randomised			Analysed at 24 months		
	Overall	Z250	Vitremer	Overall	Z250	Vitremer
N	55	28	27	44	21	23
Male, n (%)	24 (44)	12 (43)	12 (44)	19 (43)	8 (38)	11 (48)
Female, n (%)	31 (56)	16 (56)	15 (56)	25 (57)	13 (62)	12 (52)
Age (months), mean (SD)	80.7 (15.5)	80.5 (15.3)	81.0 (16.0)	78.9 (14.9)	78.6 (15.1)	79.3 (15.0)
Restorations/patient						
One, n (%)	17 (31)	8 (29)	9 (33)	12 (27)	5 (24)	7 (30)
Two, n (%)	22 (40)	12 (43)	10 (37)	18 (41)	9 (43)	9 (39)
Three, n (%)	5 (9)	3 (11)	2 (7)	4 (9)	2 (10)	2 (9)
Four, n (%)	8 (15)	5 (18)	3 (11)	7 (16)	5 (24)	2 (9)
Five, n (%)	2 (4)	0 (0)	2 (7)	2 (5)	0 (0)	2 (9)
Six, n (%)	1 (2)	0 (0)	1 (4)	1 (2)	0 (0)	1 (4)

SD standard deviation

Table 2 Assessment of the restorations using the USPHS criteria

Criterion		12 months				24 months			
		A	B	C	P*	A	B	C	P*
1. Restoration presence	Z250	54 (100%)	–	0 (0%)	1.00	46 (94%)	–	3 (6%)	0.34
	Vitremer	58 (98%)	–	1 (2%)		54 (98%)	–	1 (2%)	
2. Marginal Integrity	Z250	52 (96%)	2 (4%)	0 (0%)	0.27	40 (87%)	5 (11%)	1 (2%)	0.21
	Vitremer	52 (90%)	6 (10%)	0 (0%)		39 (72%)	13 (24%)	2 (4%)	
3. Integrity of contact point	Z250	54 (100%)	0 (0%)	0 (0%)	0.12	45 (98%)	0 (0%)	1 (2%)	0.03
	Vitremer	54 (93%)	4 (7%)	0 (0%)		44 (85%)	6 (12%)	2 (4%)	
4. Gingival health	Z250	46 (85%)	8 (15%)	–	0.002	34 (74%)	12 (26%)	–	0.005
	Vitremer	58 (100%)	0 (0%)	–		51 (94%)	3 (6%)	–	
5. Occlusion	Z250	54 (100%)	–	0 (0%)	–	46 (100%)	–	0 (0%)	–
	Vitremer	58 (100%)	–	0 (0%)		54 (100%)	–	0 (0%)	
6. Secondary caries	Z250	52 (96%)	–	2 (4%)	0.23	41 (87%)	–	6 (13%)	0.51
	Vitremer	58 (100%)	–	0 (0%)		50 (93%)	–	4 (7%)	
7. Occlusal wear	Z250	54 (100%)	0 (0%)	0 (0%)	0.12	46 (100%)	0 (0%)	0 (0%)	< 0.001
	Vitremer	54 (93%)	4 (7%)	0 (0%)		41 (76%)	12 (22%)	1 (2%)	
Cumulative all-cause failure		No failure	Failure		P*	No failure	Failure		P*
Z250		52 (96%)	2 (4%)		0.61	46 (84%)	9 (16%)		1.00
Vitremer		58 (98%)	1 (2%)			41 (84%)	8 (16%)		

*P value from Fisher's exact test

Vitremer restoration had been lost at the 12-month follow-up while three Z250 restorations were absent at the 24 month evaluation (Table 2).

Outcomes and estimation

The majority of the restorations examined semi-annually up to 24 months were rated Alpha. For most of the parameters assessed, there were no statistically significant differences between the two groups.

Regarding marginal integrity, all restorations were evaluated as A at the 6-month follow-up. At the 12- and the 24-month evaluations, 2 and 5 Z250 restorations as opposed to 6 and 13 Vitremer restorations, respectively, were rated as B. The difference between the two groups was not statistically significant. The 1 and 2 year rating of the restorations for marginal integrity are further shown on Table 2.

Regarding the contact point integrity, there was one Z250 restoration (2%) rated as C at the 24-months follow-up, while, 7% and 12% of the Vitremer restorations were rated B at the 12- and 24-month evaluation respectively. There were 2 Vitremer restorations rated as C at the 24 months evaluation. The 12- and 24-month ratings are further shown in Table 2.

Regarding the gingival health, there were statistically significant differences in favour of Vitremer both at the 12- and the 24-month evaluations and the data are presented in Table 2. Secondary caries however, was seen in 6 (13%) Z250 and 4 (7%) Vitremer restorations at the final follow-up. As seen in Table 2 together with further data for the 12- and the 24-month evaluation, the difference was not statistically significant. When occlusal wear was evaluated, 4 (7%) and 12 (22%) Vitremer restorations were rated as B at the 12-, and 24-month evaluation respectively. One (2%) Vitremer restoration was rated as C at the 24-month evaluation. All Z250 restorations were rated as A during the 24-month follow-up period. The difference was statistically significant (Table 2).

The cumulative all-cause failures after 2 years were 8 (16%) for the Z250 and 9 (16%) for the Vitremer restorations, equal for the two materials (Table 2). Tables 3 and 4 provide the results of the univariable and multivariable regression as RRs and their 95% CIs. After taking into account clustering effects and confounding in the multivariable model, no statistically significant difference could be seen between the two materials for all-cause failure (i.e. failure of at least one USPHS criterion; RR = 1.56; P = 0.20). A trend close to significance was seen for higher failure of the contact point integrity criterion with Vitremer compared to Z250 (RR = 7.17; P = 0.07). On the other hand, teeth restored with Vitremer had significantly better gingival health compared to teeth restored with Z250, as seen by the corresponding criterion (RR = 0.24; P = 0.03). Finally, occlusal wear could be perfectly predicted by the choice of material, since only teeth restored with Vitremer were graded as B or C.

Table 3 Results of the univariable binary regression on factors associated with failure criteria

	Material	
	Z250	Vitremer
All-cause failure		
RR (95% CI)	Referent	1.56 (0.79,3.09)
P		0.20
1. Retention		
RR (95% CI)	Referent	0.32 (0.03, 3.70)
P		0.36
2. Marginal integrity		
RR (95% CI)	Referent	2.42 (0.76, 7.68)
P		0.13
3. Contact point integrity		
RR (95% CI)	Referent	7.75 (0.90, 66.60)
P		0.06
4. Secondary caries		
RR (95% CI)	Referent	0.65 (0.15, 2.77)
P		0.56
5. Gingival health		
RR (95% CI)	Referent	0.24 (0.06, 0.97)
P		0.05
6. Occlusal wear		
RR (95% CI)	Referent	Predicts perfectly
P		NC

RR relative risk, *CI* confidence interval, *NC* not calculable

Discussion

Interpretation of findings

The results of the present 2-year single-centre blinded randomised clinical trial indicate that no statistically significance difference in the overall performance (all-cause failure) of composite resin or RMGIC used for Class II primary molar restorations can be found, although differences in specific USPHS criteria seem to exist. Requirements for materials used for restoring the primary dentition may differ from those for permanent teeth. Except for the extent of the carious lesion, the choice should take into consideration factors such as the age and cooperation of the patient while adjusting for the increasing aesthetic demands. In addition, the easier insertion technique and decreased chair time are regarded as advantages in a restorative material for primary teeth. Consequently, the selection of the appropriate restorative material for primary teeth remains a challenge for the clinician. Both composite resin and RMGIC are widely used for the restorations of primary molars (Milsom et al. 2002; Mjör et al. 2002).

While the annual failure rates of composite resin restorations in primary molars range between 0 and 15% (Espelid et al. 1999; Honkala et al. 2003), RMGICs show somewhat lower annual failure rates that range between 0.8 and 10% (Donly et al. 1999; Espelid et al. 1999; Hübel and Mejàre 2003). In the prospective study of Folkesson et al. (1999) the failure rate in Vitremer restorations was 8.1% for the first year, 11.7% for the second and 19.8% for the third year. The most common reasons for failure were secondary caries and loss of retention. The factors possibly contributing to the clinical behaviour of these materials are the higher polymerisation shrinkage of the composite resin, the better adhesion of the RMGI to the cavity walls, and the fluoride release of the RMGI (Fuks et al. 2000). In the present trial, the cumulative all-cause failures after 2 years were equal for

Table 4 Results of the univariable binary regression on factors associated with failure criteria (please check the lit on this point)

	Factor								
	Material		Gender		Age	Jaw		Molar	
Category	Z250	Vitremer	Male	Female	Per year	Upper	Lower	2nd	1st
All-cause failure									
RR (95%)	Referent	1.36 (0.76, 2.44)	NT	Referent	0.98 (0.96, 1.00)	0.71 (0.40, 1.28)	Referent	NT	Referent
P		0.30	NT		0.13	0.26		NT	
1. Retention									
RR (95%)	Referent	00.28 (0.02, 4.16)	NT		1.07 (0.98, 1.16)	NT		NT	
P		0.36	NT		0.12	NT		NT	
2. Marginal integrity									
RR (95%)	Referent	2.32 (0.83, 6.50)	1.73 (0.66, 4.54)		0.97 (0.93, 1.02)	NT		1.82 (0.89, 3.71)	Referent
P		0.11	0.27		0.23	NT		0.10	
3. Contact point integrity									
RR (95%)		7.17 (0.85, 60.47)	NT		1.05 (1.01, 1.10)	NT		NT	
P		0.07	NT		0.02	NT		NT	
4. Secondary caries									
RR (95%)		0.69 (0.15, 3.11)	NT		0.97 (0.92, 1.01)	NT		NT	
P		0.63	NT		0.14	NT		NT	
5. Gingival health									
RR (95%)	Referent	0.24 (0.07, 0.86)	NT		0.93 (0.89, 0.97)	NT		NT	
P		0.03	NT		0.001	NT		NT	

RR relative risk, *CI* confidence interval, *NT* not tested

the two materials, 8 (16%) for the Z250 and 9 (16%) for the Vitremer restorations.

The young age of the patients may contribute to increased failure rate. The lack of appropriate isolation or the limited cooperation of the patient may lead to a reduced quality of the restoration (Antony et al. 2008). In this trial the children were relatively young. Nevertheless, local analgesia and a rubber-dam isolation were used for all the restorations, while uncooperative patients (Frankl 1, 2) were excluded, reducing the influence of the age factor on the results.

Composite resin is a popular restorative material for carious lesions in primary molars. Its satisfactory adhesion, aesthetics, and physico-mechanical properties enable composites to be used in posterior teeth. Nevertheless, these materials require a longer working time and are regarded as technique sensitive, making their use more demanding for younger patients. The success rates of composite resin are comparable to amalgam in short term studies, but may be questioned in long term studies. Hse and Wei (1997) reported a failure rate of 1.7% of the hybrid composite Prisma TPH 1 year after placement, while Varpio (1985) reported a success rate for composites of 86% for the first year and a median survival rate of 32 months. Loss of retention is reported as one of the main disadvantages of the material (Fuks et al. 2000). In the present trial, three Z250 restorations were lost at the 24 months evaluation, while one Vitremer restoration was lost at the 12 months evaluation, with no statistically significant difference between the two materials.

Poor marginal adaptation is also cited as a main cause of failure in composite resin. In the study of Granath et al. (1992), the main reasons for failure were marginal adaptation and discolouration at the margins. These findings are mainly related to polymerisation shrinkage, which still remains a deficiency of the material (Fuks et al. 2000). However, in this trial, marginal integrity was rated as A for 87% of the Z250 restorations. The corresponding rate for Vitremer was 72%, with the difference between the two materials not being statistically significant.

Studies on the use of composite resin highlight secondary caries as an important reason for restoration replacement (Fuks et al. 2000). Although greatly reduced within a week or two after mixing, fluoride release by the RMGIC is regarded as continuous, possibly resulting in a cariostatic effect. Donly et al. (1999) found that Vitremer presented with less demineralisation than amalgam in the proximal surface of class II primary molar restorations and this was further supported by intra-oral findings (Kotsanos 2001). Fluoride release values for RMGIC range from 50 to 600 mg/cm^2 and are significantly higher than those for composite resin which range from 0 to 10 mg/cm^2 (Hickel 1996). This indicates that RMGIC might be more appropriate for

children with high caries susceptibility (Fuks et al. 2000). In the present study, secondary caries was the main reason of failure. In particular, 2 (4%) and 6 (13%) teeth with Z250 presented secondary caries at the 12 and 24 months evaluations respectively, in comparison with 0 and 4 (7%) teeth in the RMGIC group, with the difference between the two materials not being statistically significant.

One criterion that showed a significant difference between resin and RMGIC restorations was gingival health. A higher percentage of composite restorations presented with bleeding on probing, both at the 12 and the 24-months recall visits. The generalised linear model also indicated a lower relative risk of poor gingival health using Vitremer rather than Z250. According to the study of Santos et al. (2007), RMGIC had a stronger effect on the subgingival biofilm composition than composite resin. The study of Atieh (2008), reported that open-sandwich restorations exposing Vitremer in their proximal aspect were conducive to statistically significantly better gingival health in comparison with preformed metal crowns.

Light-cured materials are associated with uncured layers of resin in deeper cavities. Incremental placement of the material is proposed to overcome this drawback. Vitremer is a so called 'tri-cure' RMGIC, the third curing procedure being initiated with the mixing of the powder and liquid and continuing in the dark, thus allowing the curing of the material in the deeper layers. While wear resistance and fracture toughness have been improved in comparison to conventional glass ionomer cement (Mitra and Kedrowski 1994; De Gee et al. 1996), clinically noticeable occlusal wear remains as a disadvantage in Vitremer and possibly with any sizeable RMGIC restoration (Kotsanos and Arizos 2011). Regarding the occlusal wear in the present trial, 12 (22%) of the Vitremer restorations were rated as B and 1 (2%) as C at the 24 months assessment, while all Z250 restorations were rated as A. The difference between the two groups was statistically significant. However, restorations rated as B for occlusal wear by Cvar and Ryge criteria (i.e. no exposed cut tooth structure) do not probably bear clinical significance for primary molars.

Limitations

The fact that the present study was conducted in a single centre might have limited the variability of its sample. As however, the university's Paediatric Dentistry Clinic receives a large number patients of variable age, nationality, socioeconomic level, and dental needs, this contributes to the sample's diversity. Furthermore, blinding of treatment providers and outcomes assessors was impractical to be strictly implemented, since they were experienced clinicians calibrated in the handling/assessing of both materials. Finally, as only cooperative children were included in the trial, the results of the trial might not be directly extrapolated to non-cooperative children.

Generalisability

The results of the present trial are applicable to the majority of healthy cooperative children of mostly Caucasian descent, aged 4.0–7.5 years old with at least one primary molar in need of Class II restoration.

Conclusions

Both Vitremer and Z250 presented acceptable clinical behaviour at the 24 months follow-up. The overall success rate for both materials was 84% after 2 years. There were no statistically significant differences in any parameters other than gingival health (in favour of Vitremer), and occlusal wear (in favour of Z250).

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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