Restoration of class II cavities in primary molar teeth with conventional and resin modified glass ionomer cements: a systematic review of the literature

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Abstract
Aim: To review the literature concerning the restoration of primary teeth with glass ionomer (GIC) or resin modified glass ionomer cement (RMGI) used in conventional class II cavities. **Methods:** A search of the literature identified through Medline between 1966 and 2006 using the key words: glass ionomer, resin modified, glass polyalkenoate, deciduous/ primary teeth. Studies that used ART or tunnel preparations were excluded. Papers of relevant clinical studies (prospective and retrospective) were assessed and graded using predetermined criteria. Papers were graded according to the number of criteria met as (A >90%, B1 = 75%, B2 = 50%, C < 50%). **Results:** The search identified 411 papers, from which an application of the inclusion criteria yielded 20 studies. Of these, 2 were rated B1 and 18 B2. Failure rates varied from 6.6% to 60% for GIC, and from 2% to 24% for RMGI. **Conclusion:** GIC cannot be recommended for class II cavities in primary molars. There is evidence that RMGIC can perform successfully in small to moderate sized class II restorations.

Introduction
A dramatic reduction in caries rates for permanent teeth has been reported in many industrialised countries in the past decades, but for primary teeth this fall in caries has not occurred [Poulsen and Pedersen 2002; Pitts et al., 2006]. Determining appropriate restorative interventions for carious primary teeth, therefore, remains an important issue for clinicians.

Traditionally, amalgam was the material of choice for posterior teeth (both primary and permanent), throughout the world. However, in the past 20 years the development of tooth coloured materials and concerns over potential mercury toxicity has lead to an increase in alternative restorative materials being used by dentists and requested by patients [Osborne and Albino 1999; Mjor et al., 2002; Peretz and Ram 2002].

Glass ionomer cement (GIC) has been available for over 30 years [Wilson and Kent, 1972] and has a number of potential advantages over amalgam such as fluoride (F) release, chemical bonding to tooth structure and good biocompatibility [Mount, 1994; de Araujo et al., 1996]. However, conventional GIC are slow setting and have low fracture toughness and poor wear resistance [Hickel and Manhart, 1999]. Despite these disadvantages GIC is the restorative material of choice for general dental practitioners restoring the primary dentition [Qvist et al., 1990; Mjor et al., 2002, Milsom et al., 2002] although it has been shown to be inferior to amalgam in clinical trials [Welbury et al., 1991; Ostlund et al., 1992] and more recently in a systematic review [Chadwick et al., 2001].

Recently, because of its adhesive properties and ability to be placed without the use of electrical equipment, GIC has been used in the atraumatic restorative treatment (ART) technique, which was developed for less-industrialised countries where extraction is the norm and restorative care is rare [Frencken et al., 1996]. A recent review of ART shows it to be a useful technique for class I lesions but not for multisurface cavities [Foley, 2006].

Resin-modified GICs (RMGIC) were developed to overcome the reported problems of the conventional GIC material and show better wear resistance and higher fracture toughness [Uno et al., 1994; de Gee et al., 1996]. Unlike GICs, which set via an acid-base reaction, RMGICs initially set through resin polymerization thus improving the setting time without affecting handling properties. Studies comparing the two materials suggest that RMGICs are superior [Hubel and Mejare, 2003; Qvist et al., 2004b].

The purpose of the present review was to assess the literature to date relating to the success of both GIC and RMGIC in the restoration of class II cavities in primary molars using the approach published in the European Archives of Paediatric Dentistry [Curzon and Toumba, 2006]. Because a recent review has addressed both ART and Tunnel restoration [Foley, 2006] this review only considered conventional cavity preparations

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Methods

Literature search. The relevant reports published between 1966 and 2006 were identified using OVID Medline and EMBASE. A combination of MeSH headings, key words and phrases were used. The keywords used were:

- glass ionomer cement,
- glass polyalkenoate cement,
- glass polyalkenoate cement,
- fluoride containing restoration,
- deciduous tooth,
- permanent dental restoration.

The search was restricted to reports written in English, clinical or retrospective studies and study populations of children under 18 years. The reference section of obtained reports was searched to identify other studies.

Exclusion criteria. Studies were excluded if they were: laboratory based, questionnaire based, only reported GIC or RMGIC in ART, tunnel or sandwich restorations, results were only reported at less than 24 months. Where doubt existed over the exclusion of a study based on the title or abstract it was retrieved.

Inclusion criteria. Studies were included if they reported prospective or retrospective clinical studies, conventional primary molar restorations of GIC or RMGIC, 90% or more of restorations reported results after at least 24 months.

Assessment criteria. These were based on those of Curzon and Toumba, [2006] with modifications relevant to the restorations under review. These modifications were made after discussion with the authors of the systematic review of amalgam restorations published simultaneously [Kilpatrick and Neumann, 2007]. Only studies reporting the majority of results after 24 months were included. Half marks were given for incomplete reporting. For example, if patients were randomly allocated, but details of randomisation were not supplied, only half a mark was given (criteria13); similarly, taking but not standardising radiographs only scored half marks (criteria 14). A decision was taken to record sponsorship but not to score a mark for it. Instead the information was reported in the data extraction tables, as this category was not deemed appropriate for all study designs. Thus there were 22 criteria listed which are given in Table 1 of Kilpatrick and Neumann, [2007]. All studies were graded independently by two reviewers, with disagreements being resolved by consensus.

Grading. All included papers were graded according to the number of points scored using the modified criteria as follows:

Grade A = 90% or better (20/22),

Grade B1 = 75% (16.5 to 19.5/22),

Grade B2 = 50% (11 to 16/22),

Grade C = <50% (less than 11/22).

Results

Literature search. The initial searches yielded 411 titles and abstracts, of which 379 were excluded at the first stage. The remaining 32 papers were retrieved, and a further 10 were excluded (4 case reports/no data, 4 not relevant, 1 questionnaire survey, 1 follow up 12 months). Thus, 22 papers reporting 20 separate studies undertaken in 9 countries were included. These were 15 clinical trials (of which 10 were split mouth studies), 4 were prospective and 1 was a retrospective study. GIC and RMGIC materials were used in 12 and 10 studies respectively; two papers reported on both GIC and RMGIC.

Grading. Following application of grading criteria no study was graded category A. Two studies were graded as B1 (18 and 17/22 criteria) the remainder were graded B2 (range 11 to 16/22 criteria). The papers are listed in Tables 1 and 2 and, where possible, results for class II restorations have been recorded.

*Grade B1 (Table 1).*The highest scoring paper (18/22) was a split mouth randomised controlled trial (RCT). Hübel and Mejàre [2003] reported on 40 consecutively attending children, of whom 33 had paired class II lesions in primary molar teeth. Lesions were randomly restored with either GIC (Fuji II) or RMGIC (Vitremer) by a single operator in the Pedodontic Department of the Eastman Dental Institute in Stockholm (Sweden) with local analgesia (LA) but not rubber dam (RD). This well planned study omitted criteria 3, 5 and 21. The examiners were calibrated for both clinical and radiographic criteria but as one of them was both operator and examiner blinding cannot be assumed (criteria 16). The authors report a statistically significant difference in favour of RMGIC at 36 months ($p<0.05$).

A second randomised controlled split mouth study scoring 17/22 was reported by Kotsanos and Dionysopoulos [2004]. This study, based in a Greek private practice, was actually undertaken to investigate the caries preventive effect of RMGIC (Vitremer) on adjacent enamel with the use of F-toothpaste and biannual Duraphat varnish application, but the reporting allows the success rate of the RMGIC to be deduced. Both LA and RD were used for all restorations. As with the previous report, power calculations and exclusion criteria were not given. Criteria 3, 5, 17 and 18 were omitted and a 1/2 mark scored for criteria 13 and 21.

The reported failure rate of 2.4% after 24 months is impressive but the drop out rate was very high with 56% of the subjects lost from the study.

Grade B2 (Table 2). The remaining 20 papers (18 studies) all received this grading. Of these, the highest scoring (16/22) was a split mouth RCT reporting 60 month results of amalgam (AM) versus GIC (Ketac-Fil) in a study undertaken in Newcastle Dental School [Welbury et al., 1991]. The 24 month results are included in the link paper Walls et al. [1988]. In this study RD was not used but LA was used if required. Although this is the same study, the earlier report only scores 13/22, illustrating that the reporting details can be very influential in determining apparent study quality. Although the earlier report found that both GIC and AM were comparable after 24 months, by 60 months a statistical difference in favour of AM was found (P<0.01) with a third of GIC restorations failing. The median survival time (MST) for GIC was also lower; 33.4 compared with 41.4 months. It should be noted that 16 pairs in this study were class I cavities. Because of the recruitment method, some restorations in each paper had been in place less than 24 months, but the majority had been in place at least 24 months. The reports omit criteria 3, 7, 11, 14, 21 and blinding was not possible (criteria 16). The earlier report failed to adequately report criteria 5, 10, and 18.

An interesting series of papers using the same study design to investigate a series of different materials in large trials in Public Dental Health Service (PDHS) clinics in Denmark all scored 15.5 or 15/22 [Qvist et al., 1997; Qvist et al., 2004abc]. In these studies, all operators in the PDHS used the designated trial materials for all restorations in primary teeth, in sequence, for 1 week blocks over periods of between 4 and 15 months. In each case, an ongoing lecture program supported the study; RD was not used. The missing criteria in each case were the same; no power calculation was given (criteria 3), although given the sample size the calculation might be considered redundant. In addition, criteria 14, 16-18 and 21 were not reported. Criteria 15 was not explicitly stated and only scored a 1/2 mark. The two lower scoring studies [Qvist et al., 2004b and c] only scored 1/2 for criteria 12.

The first study compared AM with GIC (Ketac-Fil®) reporting results at 36 and 96 months [Qvist et al., 1997; Qvist et al., 2004a]. A total of 1,058 restorations were placed with LA and no RD in a range of cavities types by 14 dentists. Results for class II cavities alone are reported, with GIC showing a higher failure rate (p<0.001). Patient drop out was very low (4% GIC group; 8% AM group). Amongst class II cavities, tooth or restoration fracture was the most common reason for failure of GIC (26%). The 96 month results report an overall failure rate of 46% (compared with 22%) for GIC, with a MST for GIC of 42 months (compared to 7.8 years for AM). Although the GIC were found to reduce the need for operative treatment the authors concluded that their high failure rate made them unsuitable for restorations in primary teeth.

Results of a 96 month study using 16 PDHS dentists comparing GIC (Ketac-Fil®) and RMGIC (Photac-Fil®) from the same research group [Qvist et al., 2004b] found 46% of GIC and 36% of RMGIC class II restorations failed during the study period. Use of LA and moisture control was not reported. Fracture and loss of retention were the major causes of failure for both materials. The 50% survival time for restorations (all types) were 55 months for RMGIC and 48 months for GIC (p<0.01). The authors also looked at cariostatic effects of the two materials, concluding that both materials showed similar cariostatic effects on restored teeth and adjacent surfaces. RMGIC was recommended for class II restorations but GIC was found to have superior longevity for class III/V cavities (18% GIC failure versus 47% RMGIC).

In the third study from this group [Qvist et al., 2004b] 15 dentists placed 1,565 class II cavities, although once again use of LA and information on moisture control were omitted from the

Table 1 Studies of GIC and RMGIC graded B1.

Author Year	Rating Country	Design	Groups (Control) Active	Number Rest (pt)	Operator Training (setting)	Examiner (Calib)	Study length (mnths)	Subject Ages (years)	Failure Rate Test	Failure Rate Control	Comments
Hubel and Mejare, 2003	18/22 Sweden	RCT (Split mouth)	GIC RMGI	62 (40) 53	1 Specialist (Hospital)	At least 2 (yes)	36	4-7 Mean 6.2	11/62 18% (GIC) 2/53 4% (RMGI)	-	Sponsorship declared Operator – examiner 33 children paired restorations
Kotsanos and Dionysopoulos, 2004	17/22 Greece	RCT (Split mouth)	(Mixed) RMGI	41 (36) 41	1 Specialist (PP)	1 (N/A)	24	4-7	1/41 2.4%		Operator-examiner 47 of 83 children excluded Results based on 36 children Different examiner for radiographs

Table 2 Studies of GIC and RMGIC graded B2, ranked according to assessment score.

Author Year	Rating Country	Design	Groups (Control) Active	Number Rest (pt)	Operator Training (setting)	Examiner (Calib)	Study length (mnths)	Subject Ages (years)	Failure Rate Test	Failure Rate Control	Comments
Welbury et al. 1991 (link Walls)	16/22 UK	RCT (split mouth)	(Amal) GIC	119 (76) 119	2 Specialist (Hospital)	2 (Yes)	60	5-11	39/119 33%	24/119 20%	Operator – examiner Material order not random Sponsorship declared 16 pairs class I
Walls et al. 1988	13/22 UK	RCT (split mouth)	(Amal) GIC	58 (43) 58	1 Specialist (Hospital)	1 (N/A)	24	5-11	14%	20%	Operator – examiner Material order not randomised Sponsorship declared 11% fillings at 18/12
Qvist et al. 1997	15.5/22 Denmark	RCT	(Amal) GIC	456(666) 384	14 non specialist (PDHS)	14 (trained)	36	3-13 (Med 7)	42%	18%	Sponsorship declared, Operator – examiners 191/515 (37%) & 76/543 (18%) failures overall
Qvist et al. 2004a (link Qvist et al. 1997)	15.5/22 Denmark	RCT	(Amal) GIC	456(666) 384	14 non specialist (PDHS)	14 (trained)	96	3-13 (Med 7)	177/384 46%	102/456 22%	Median survival GIC 42months; Amalgam 7.8 years. All cavity types reported
Qvist et al. 2004b	15./22 Denmark	RCT	GIC RMGIC	320 (640) 371	16 non specialist (PDHS)	16 (Trained)	96	3-17.5 Mean 7.5	146/320 46%	132/371 36%	Operator – examiners Sponsorship declared Class I, III, V cavities also reported
Qvist et al. 2004c	15./22 Denmark	RCT	(Comp) RMGI (F) RMGI (P) RMGI (V)	385 (971) 413 393 347	15 non specialist (PDHS)	15 (Trained)	84	3.6-14.9 Med 8.1	Condition + - 19% 19% 20% 24% 14% 19%	Condition + - 9% 39%	Operator – examiners Sponsorship declared
Folkesson et al. 1999	15/22 Sweden	Pros	RMGI	174 (85)	6 non specialist (PDHS)	6 (Yes)	36	4-12 Mean 7.10	19.8%	-	Operator – examiners Sponsorship declared
Welbury et al. 2000	15/22 UK	RCT (split mouth)	(Comp) GIC	56 (29) 56	2 Specialist (Hospital)	1 (N/A)	42	4-9 Mean 6.7	12/56 21.5%	2/56 5.4%	31 pairs were class I Operator – examiner Sponsorship declared
Roberts et al. 2005	15/22 UK	Pros	(SSC) RMGI (NS)	1107 1088	1 Specialist (PP)	1 (N/A)	Max 80 Mean 20	1.9-15.4	51/962 5.3%	3%	Operator – examiner 126 class II not reviewed. 25 class II replaced due to caries at fresh site.
Espelid et al. 1999	14.5/22 Norway	RCT (split mouth)	(Cermet) RMGIC	49 (37) 49	2 NS (NS)	2 (trained)	36 (Mean 7.8)	5-11	1/49 2%	13/49 27%	Only “small, early dentinal lesions” included
Attwood et al. 1994	14/22 UK	Pros	GIC	635 (606) 360 Cl II	9 non specialist (PDHS)	2 (Yes)	36	NS	170/360 47%	-	Variable technique, Class I & V cavities reported
Fuks et al. 2000	14/22 Brazil	CT	(Amal) (Co) RMGI	24 (29) 38 40	1 NS (NS)	4 (No)	36	8-10	Cannot Deduce ?2/40	Cannot Deduce ?1/38 ?0/24	All 3 materials satisfactory to 24 months

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Table 2 Continued.

Author Year	Rating Country	Design	Groups (Control) Active	Number Rest (pt)	Operator Training (setting)	Examiner (Calib)	Study length (mnths)	Subject Ages (years)	Failure Rate Test	Failure Rate Control	Comments
Donly et al. 1999	13./22 USA	RCT (split mouth)	(Amal) RMGIC	NS (40) NS	1 Specialist (NS)	NS	36	6-9	Cannot Deduce	Cannot Deduce	Operator – examiner, 25% drop out at 6/12. Cannot deduce results but no sig diff between groups
Rutar et al. 2000	13/22 Australia	Pros	GIC	129 (69) 72 Cl II	1 Specialist (Hospital)	NS	24	5-8 Mean 6.7	6.6%	-	Sponsorship declared ?operator – examiner 0% failure cl I
Rutar et al. 2002 (link Rutar)	13/22 Australia	Pros	GIC	129 (69) 72 Cl II	1 Specialist (Hospital)	NS	36	5-8 Mean 6.7	6.6%	-	Very high drop out at 3rd year
Yu et al. 2004	13/22 China	RCT (split mouth)	(ART F) (ART KM) GIC (F) GIC (KM)	15 (60) 20 7 11	2 NS (Hosp)	1 (NS)	36	7-9 Mean 7.4	21.7% 10.5%	13.8% 11.1%	Complex study design, 60 patients also included class I restorations 27 ART, 45 GIC and 32 amalgam.
Ostlund et al. 1992	12.5/22 Sweden	CT	(Amal) (Co) GIC	25 (50) 25 25	2 NS (PDHS)	2 (Yes)	36	4-6	60%	8% 16%	Operator – examiner
Kilpatrick et al. 1995	12.5/22 UK	RCT (split mouth)	(Cermet) GIC	46 (37) 46	1 Specialist (Hospital)	1 (N/A)	30	5-11 (Mean 7.8)	11/46 24%	19/46 41%	Operator – examiner Sponsorship declared
Andersson et al. 1995	12/22 Sweden	CT (split mouth)	GIC Micro GIC Blacks	28 (25) 28	2 NS (PDHS)	NS	36	6-10 (Mean 8)	25% 32%	-	Test micro Class II cavity (no lock) vs modified Blacks cavity
Croll et al. 2001	11/22 USA	Retro	RMGI	864 (306) 406 Cl II	1 Specialist (PP))	1 ass (N/A)	36 Min	1-10	27/406 6.7%	-	Operator – examiner assumed. Small to moderate sized lesions

RCT = randomised controlled trial; Ct = Clinical trial; Pros = prospective; Mixed = Amalgam and Composite; Amal = amalgam; Co = composite; Comp = compomer; Med = median; Min = minimum; PDHS – Public Dental Health Service; PP = Private practice; Ass = assumed; NS = Not specified

report. One compomer (Dyract®) and three RMGIC (Fuji II LC®, Photac Fil®, Vitremer®) were tested with and without their respective cavity conditioners, giving 8 groups of class II restorations. Multivariate survival analyses showed that the restorative material and cavity conditioning influenced the survival of restorations but not the progression of caries on unfilled adjacent surfaces. For two materials (Dyract® and Vitremer®) conditioning the cavities statistically improved restoration survival. Failure was increased for endodontically treated teeth and replacement restorations. The clinician placing the restoration influenced the failure rate more than the material used or conditioning. The MST exceeded 5 years for all groups and the authors concluded that all four materials were suitable for class II restorations in primary teeth.

Three other studies scored 15/22. Welbury et al. [2000] used a split mouth design to compare a compomer (Dyract®) with GIC (Chemfil Superior®) in Newcastle Dental Hospital (England). Of the 56 pairs placed, 31 were occlusal cavities, 35 pairs were placed under general anaesthetic and 21 with LA; RD was not used. The mean MST's were 37 months for GIC and 42 months for compomer, the difference being statistically significant at the 5% level. The missing criteria were 7, 11, 14, 16-18 and 21. Folkesson et al. [1999] reported on a prospective study of RMGIC (Vitremer®) undertaken by 6 trained PDHS dentists; RD was not used. Annual reviews were undertaken and cumulative failure rates of 8.1%, 11.7% and 19.8% were reported. The drop out rate in this study was very low. The most common reasons for failure were secondary caries and loss of retention. The missing criteria were 3, 5, 7, 14, 16, 18 and 21.

Finally a prospective study based in a private practice scored 15/22. Roberts et al. [2005] reported the results of all molar restorations placed by a single operator over a 6 year period. This included 1,088 minimal class II restorations

restored with RMGIC (Photac-Fil®), of which 962 were subsequently reviewed. Almost all restorations were placed under RD dam while 863 were placed under LA and 183 with general anaesthetic. During the review period, 26 restorations failed (2.4%) and 25 were replaced because of caries at a new site (2.3%). The un-met criteria were 3, 7, 11, 16-18 and 21.

With a score of 14.5/22, Espelid et al. [1999] compared 49 RMGIC (Vitremer®) and cermet restorations (Ketac-Silver®) in a split mouth design over 36 months. Details of isolation and LA were not given. Over a quarter of the cermets failed compared with a single RMGIC. The MST for cermet was 37 months, while the MST for RMGIC could not be calculated because of the low failure rate, but exceeded 42 months, with the difference being statistically significant ($p<0.0003$). The missing criteria were 3, 5, 7, 16, 18 and 21. Half marks were given for incomplete reporting of 11, 12 and 14.

Two studies scored 14/22. The first reported a clinical trial comparing AM, composite resin (Z100®) and RMGIC (Vitremer®) in 29 children in a Dental School clinic in Brazil [Fuks et al., 2000]. All restorations were placed with LA and RD. Because of the age of the patients, a large number of restorations were reviewed for less than 24 months (19/40 Vitremer®, 17/38 composite resin and 15/24 AM). The authors reported good success rates for all restorations with no statistically significant differences in failure rates. However, it is difficult to determine exactly when restorations were evaluated in this study. The Vitremer® and AM restorations had significantly fewer radiographic defects than the composite resin restorations at 24 months ($p<0.002$). The missing criteria were 3, 5, 7, 16, 18 and 21 while criteria 13, 14, 17 and 22 were scored as 1/2.

A prospective study based in PDHS in Scotland also scored 14/22. Attwood and co-workers [1994] trained 9 dentists to place GIC (Chemfil II®) in different cavity types. The placement technique was variable but use of LA, lining, matrices and RD was recorded. In total, 360 of 635 (57%) of the restorations were placed in class II cavities. By the third year examination, 276 (43.5%) of restorations were lost to follow up. At 12 months the proportion of class II restorations failing compared with class I restorations was statistically significant ($p<0.05$), although the difference was not statistically significant at 36 months. The authors concluded that GIC was a suitable material for class I but not class II cavities. The missing criteria were 3, 7, 8, 13, 14, 16, 18 and 21.

Three studies scored 13/22. Donly et al. [1999] reported a clinical trial of 40 class II restorations, using a split mouth design, comparing AM with RMGIC (Vitremer®); LA and RD were used. The authors concluded that both materials were suitable for use in primary teeth and that RMGIC exhibited significantly less demineralisation at restoration margins ($p<0.001$), based on a study of 26 (32.5%) exfoliated teeth. Unfortunately it is not possible to calculate the failure rates from the data provided, and only 19 of 40 restorations remained at 36 months. The missing criteria were 3, 7, 11, 14, 16-18 and 21. Randomisation was not detailed and the setting for the project was not given, thus criteria 10 and 13 were scored as 1/2.

The results of a prospective study of a high powder: liquid ratio self-cure GIC (Fuji IX GP®) are given in two reports at 24 and 36 months [Rutar et al., 2000, 2002]. In this study RD was not used and LA was used only if the patient experienced discomfort. Of the 129 restorations placed in the Oral Health Education Unit in Brisbane (Australia), 73 were class II, with the rest occlusal restorations. A total of 69 patients were recruited. After 24 months, 10% of patients were lost to the study and 6.6% of class II restorations had failed, and at 36 months the failure rate was unchanged. The authors concluded that the survival rate of the restorations was acceptable over a 36 month period but only 46 of 113 restorations seen at 24 months were reviewed. The missing criteria were 3, 7, 11, 13, 14, 16-18, 21.

Yu et al. [2004] compared the survival of GIC restorations placed in the Beijing Medical University (China) using both the atraumatic restorative technique (ART) and conventional cavity preparation with rotary instruments, with AM restorations. They used two GIC (Fuji IX GP® and Ketac-Molar Aplicap®) in both class I and II cavities but the AM in class I cavities only. A split mouth design was used with two cavity preparation methods and random assignment of materials. Thus, 167 restorations in 9 groups were placed in 60 children. Drop out rates were high with 20% of subjects and 21.6% of restorations lost at 12 months and another 21.7% of subjects and 30% of restorations by 24 months. It is possible to deduce the failure rate for class II GIC restorations. Class II restoration survival was significantly lower for ART approach ($p<0.001$). The missing criteria were 3, 5, 7, 11, 14, 16-18, 21.

Two studies scored 12.5/22. Ostlund et al. [1992] reported a clinical trial comparing on AM, a composite resin and a GIC (ChemFil®) placed in consecutive child patients in a PDHS clinic in Sweden. Only 40% of GIC restorations were still acceptable after 36 months. Both dentists used LA and RD for all restorations. Missing criteria were 3, 7, 11, 14, 16-18, 20, 21, and because the randomisation method was not specified, 1/2 was scored for 13.

Kilpatrick et al. [1995] reported on 37 children treated using a split mouth trial of a cermet (Ketac Silver Aplicap®) and a GIC (Ketac Fil®) in Newcastle Dental School (England). All restorations were placed using LA but moisture control was not reported. Although the study lasted 30 months some teeth were censored at less than 24 months. The GIC restorations were more durable (23.9% failure rate compared with 41.3%) with an MST of 25.3 months compared with 20.3 months for the cermet ($p<0.05$). Criteria missing were 3, 5, 7, 11, 14, 16-18, 21, and because the randomisation method was not specified, 1/2 was scored for 13.

Scoring 12/22, Andersson-Weckert et al. [1995] reported a split mouth trial in Swedish PDHS clinics in Umea, comparing a GIC (ChemFil II) placed in two different class II cavity types; what they termed a microcavity (a lockless class II cavity) and a modified Black's class II cavity design. RD was not used and details of LA were not given. By 24 months 8/28 restorations of each type were lost to follow up. At 24 months, the cumulative failure rate for both cavity types was 16%, and by 36 months the failure rate for microcavities was 25% compared with 32% for Black's cavities. The authors concluded that the microcavity form was preferable. The missing criteria were 3, 5, 7, 11, 13, 14, 16-18, 21

One retrospective study scored 11/22 and was, therefore, included in the review [Croll et al., 2001]. This study reported on all RMGIC (Vitremer Core®) placed by one of the authors in a private practice in the USA; LA and RD were used for all class II cavities. A total of 406 class II restorations were included of which 379 (93.3%) were successful, with the mean age of these restorations being 49 months. The missing criteria were 2, 3, 5, 7, 13, 14-18, 20.

Discussion

This review sought to determine the success rate of GIC and RMGIC in class II cavities in primary teeth. It is disappointing to find no studies graded as A in this review; indeed only 20 studies (22 reports) of sufficient quality were included, and the highest scoring of them included just 18 of the 22 criteria. This apparent lack of quality is reflected in other systematic reviews [Waggoner, 2006; Attari and Roberts, 2006; Fuks and Papagiannoulis, 2006] using the modified approach described by Curzon and Toumba [2006].

The criteria used in this paper do have limitations. The authors relied only on the published work, and it is likely that contacting the authors of the papers would have allowed some questions to be answered. For example, F background, training of operators etc. Some criteria are only appropriate for a clinical trial, for example only 1 clinical trial [Welbury et a., 2000] included a power study to calculate an appropriate sample size, although the large sample sizes in the studies reported by Qvist et al. [1997, 2004abc] might be considered to make a power study unnecessary. Nevertheless, a number of the criteria were missing from all or most reports. For example, none of the post operative assessments were blinded. Clearly this is not possible in a prospective study or where AM was the control group, but most studies used operator-examiners who could not be blinded.

The gold standard study design is currently held to be a randomised controlled trial with blinding and independent assessment of the restorations. Such trials are typically conducted in hospital environments with very specific inclusion criteria, often over a short period of time. While these trials are important in the early stages of material development, the results from such trials are not always generalisable and high drop out rates are common [Chadwick et al., 2001]. The two highest scoring studies in this report show some of these problems; the first based on 40 patients treated in a hospital by a specialist practitioner [Hübel and Mejàre, 2003], the second, in a specialist private practice, reporting only 36 of the 85 patients that started the study [Kotsanos and Dionysopoulos, 2004]. Both studies had carefully controlled inclusion criteria ensuring that only small cavities were restored. All restorations were placed using LA and the practice based study used RD throughout. There is evidence from qualitative studies that reports based in specialist or hospital settings may be dismissed as not relevant by general dental practitioners, at least in the UK [Threllfal et al., 2005].

Conventional GIC is the restorative material of choice for the primary dentition [Qvist et al., 1990; Mjor et al., 2002; Milsom et al., 2002]. However, the failure rate for GIC in this review is very wide varying from 6.6% to 60%. In general, studies with a single specialist operator using carefully selected inclusion criteria achieved lower failure rates in the short term: Rutar et al. 6.6% at 24 and 36 months [2000, 2002]; Walls et al. [1998] 14% at 24 months and Hübel and Mejàre, [2003] 18% at 36 months. However, as the study duration increases so does the failure rate, even for specialist practitioners in hospital settings. For example, Welbury et al. [1991], reporting on the continuation of an earlier trial, found 33% failure at 60 months, Kilpatrick [1995] 24% at 42 months and Welbury et al. [2000] 21.5% at 42 months.

Perhaps the most compelling evidence comes from prospective studies and clinical trials in PDHS clinics where multiple trained operators treat a much wider range of patients and cavity types. Under these less controlled circumstances, which more accurately reflect general dental practice, the failure rate of GIC is much higher. Qvist et al. [1997] reported a study of 666 patients, much larger than most clinical trials, in which 14 operators achieved a failure rate of 42% at 36 months.

Interestingly, the two trials that compared GIC and RMGIC both found GIC to be an inferior material [Hübel and Mejàre 2003; Qvist et al., 2004b]. Two reports specifically considered the caries preventive properties of GIC, and both concluded that even when this aspect of the material was considered, they could not be recommended for use [Qvist et al., 1997, 2004ab].

This review has found a wide failure rate for RMGIC in class II cavities, from 2% at 36 months [Espelid et al., 1999] to 36% at 96 months [Qvist et al., 2004c]. In common with GIC the best results were seen in small private practices; 2.4% at 24 months [Kotsanos and Dionysopoulos, 2004], 5.3% at 72 months [Roberts et al., 2005], 6.7% at 48 months [Croll et al., 2001]. In each of these reports a specialist operator using LA and RD achieved excellent results in minimal class II cavities. Two large PDHS based studies with at least 15

non specialist operators reported success rates of between 14% and 36% [Qvist et al., 2004bc] in studies lasting at least 84 months with very low drop put rates. One report provides evidence that the use of cavity conditioners decreases the failure rate for some RMGIC [Qvist et al., 2004c]. This report also looked at the effect of the operator on the success rate and noted that this variable was more important in determining a successful restoration outcome that the use of conditioner. In other words some operators are better than others.

Conclusions

The results from this review suggest that GIC should not be used in class II cavities. There is evidence that the use of RMGIC is successful in small to moderate sized class II cavities. There is some evidence that conditioning dentine improves the success rate of RMGICs.

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