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How Well are GIC Product Labels Related to Current Systematic Review Evidence?

Abstract: Systematic reviews have been recommended as providing the best source of evidence to guide clinical decisions in dentistry. They appraise evidence from trials focused on investigating clinical effects of dental material categories, such as conventional glass-ionomer cements (GIC) or resin-modified GIC. In contrast, the general dental practitioner is introduced to these categories of materials in the form of branded or private product labels that are marketed during dental conventions or through advertisements. Difficulties may arise in recognizing material categories that have been subjected to systematic reviews, because of the multitude of product labels on the current market. Thus, the value and relevance of published systematic review evidence concerning the material categories represented by these labels may remain obscure. Based on a systematic literature search, this article identifies glass-ionomer cement product labels used during clinical trials which, in turn, were subsequently reviewed in systematic review articles (published between 15 April 2009 and 14 April 2011). This article further clarifies how these product labels relate to the systematic review conclusions. The results show that the conventional and resin-modified glass-ionomer cements that were used in most trials were marketed by GC and 3M ESPE, respectively. The conventional GICs used in most of the reviewed trials were Fuji III and Fuji IX, while Vitremer was the most commonly used resin-modified GIC. Evidence from the reviewed trials suggests that GIC provides beneficial effects for preventive and restorative dentistry. However, more trials of higher internal validity are needed in order to confirm (or disprove) these findings. Only GIC products of branded labels and none of private labels were identified, suggesting that private label GIC products have little or no research back-up.

Clinical Relevance: Dental products, such as glass-ionomers cements (GIC), can only be judged as effective when they are based on sufficient research back-up. Systematic reviews of clinical trials provide such back-up at the highest level. Thus clinicians must be able to identify GIC products for which reliable evidence from systematic reviews of clinical studies is available and know about what such evidence contains.

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Systematic reviews are described as providing objective overviews of all the evidence currently available on a particular topic of interest.[1] Such overviews cover clinical trials in order to establish where effects of healthcare are consistent and where they may vary, through the use of explicit, systematic methods aimed at limiting systematic error (bias) and reducing the chance of effect.[2] These types of reviews have been recommended as providing the best source of evidence to guide clinical decisions[3,4] and healthcare policy,[5] and they receive twice as many citations as non-systematic reviews in peer-reviewed journals.[5–7]

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Systematic reviews are defined as scientific literature reviews aimed at answering clearly formulated questions through the use of systematic and explicit methods for identifying, selecting, and critically appraising relevant research, and for collecting and analysing data from the literature.[8] In order to fulfil this function, a systematic review:

- Presents a synthesis of the acquired knowledge regarding one particular clinical question derived from all relevant studies that are identifiable at one point in time;
- Identifies the level of internal validity and the subsequent potential systematic error risk associated with the acquired knowledge;
- Provides recommendations for improving any identified shortcoming related to internal validity, for further research;
- Owing to continued further research, systematic reviews should also provide continued updates of their synthesis.

In order to achieve its objectives, a systematic review includes:

- A systematic search for studies from all known and relevant information sources;
- A selection of those studies having the highest internal validity;
- A quality assessment of studies in line with internal validity criteria and, if possible;
- A meta-analysis of the combined study data.

Through this process, systematic reviews provide the most comprehensive answers to clinical questions.

In general, systematic reviews in dentistry appraise evidence from trials focused on the clinical treatment effects associated with dental material categories; such as 'high viscosity conventional glass-

ionomer cements (GICs)', resin-modified GIC (RM-GIC) or 'polyacid-modified resin composites (Compomers)'. In contrast, these materials are introduced to the general dental practitioner in the form of specific product names or 'labels'; such as 'Fuji IX GP' (= high viscosity conventional GIC), 'Vitremer' (= RM-GIC) or 'Dyract' (= polyacid-modified resin composite), which are marketed during dental conventions, as advertisements in dental journals or through sales campaigns and promotions. Difficulties may result regarding recognition of appraised evidence regarding dental material categories, in relation to the multitude of private and branded product labels that are offered on the dental market. Thus their value and relevance in daily dental practice may remain obscure to many dental practitioners. Against this background, this article aims to identify product labels in the dental material category of *'glass-ionomer cements'* which have been investigated in clinical trials and were in turn systematically reviewed during the last two years, and to relate these labels to systematic review conclusions.

Materials and methods

In order to identify as many systematic reviews as possible the following search strategy was used:

- Consultation of the Compendium for systematic reviews related to Minimum Intervention (MI) in dentistry (**www.mi-compendium.org**)[9] online for references to relevant systematic reviews covering conventional (C-GIC) and resin-modified glass-ionomer cements (RM-GIC);
- Systematic search of PubMed for articles reporting on clinical trials, using the MeSH search term '*Glass-Ionomer Cements'[Mesh]*;
- The search was limited to the period from 15 April 2009 to 14 April 2011.
- Subsequent search, using the English text term '*Glass-Ionomer Cement'*, in the databases: Cochrane Library, Database for Open Access Journals (DOAJ); OpenSIGLE and Open-J-Gate.

Listed abstracts of articles from the search results were reviewed and articles subsequently selected on the basis of their compliance with the inclusion criteria:

- Systematic review article according to article title and abstract;
- Review topic related to C-GIC and/or RM-GIC.

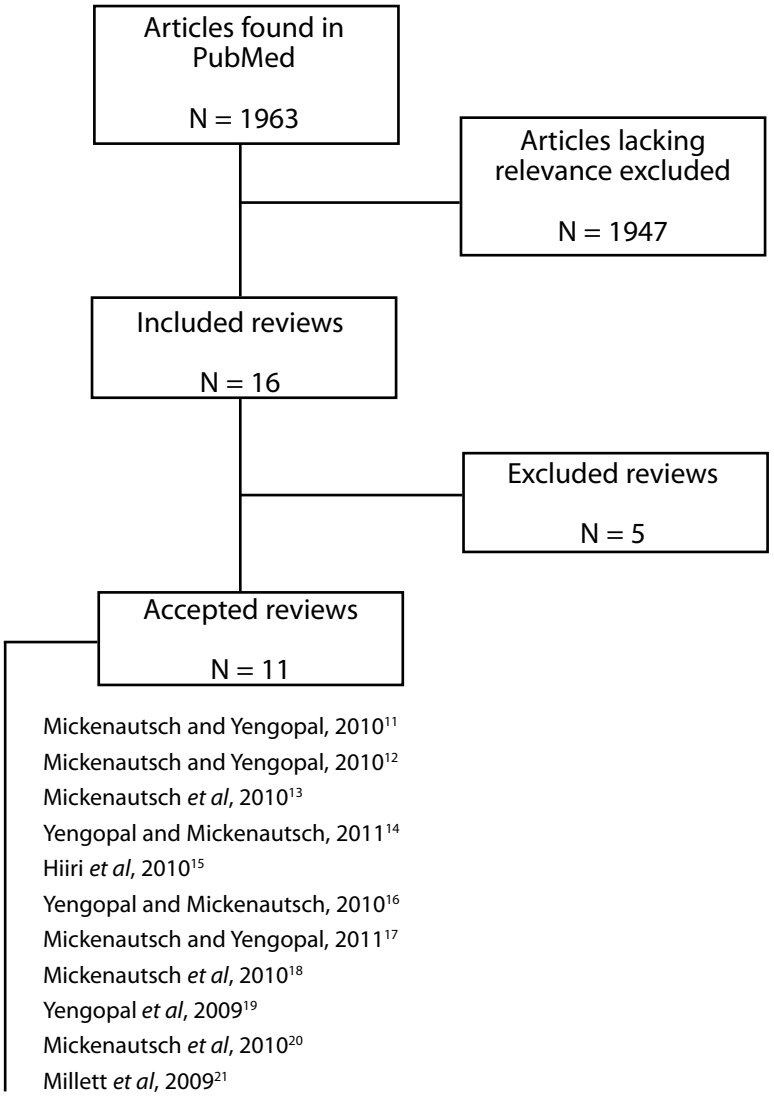

Figure 1. Flow diagram of article selection.

Where only a relevant title without a listed abstract was available, a full copy of the article was assessed for inclusion.

After completion of the search the identified articles were reviewed. Articles were not accepted if they did not comply with all the following exclusion criteria based on the QUOROM (QUality Of RepOrting Meta-analysis) recommendations for reporting systematic review methodology:[10]

- Information sources (ie databases, journal content searched) reported;
- Criteria for trial inclusion and exclusion reported;
- Criteria for trial assessment in line with internal validity aspects (ie randomization, blinding) reported;
- Trial characteristics reported.

Reviews were also excluded if they did not include any accepted trials. Updates of systematic reviews were chosen above the older, original review articles. From each accepted systematic review the following information was extracted:

- Number of trials and the labels of glass-ionomer cement products investigated in each trial;
- Labels of C-GIC and RM-GIC products,

Systematic review	Trials Reviewed**	ns	exp	C-GIC labels												RM-GIC labels						
				3M ESPE				GC			Dentsply				ns	3M ESPE			GC			Vivadent
				Ketac Cem	Ketac Fil	Ketac Molar	Ketac Silver*	Fuji II	Fuji III	Fuji IX	Chem Fil	Chem Flex	BS	AS	IN	Photac Fil	VB	VM	Fuji II LC	Fuji III LC	Fuji Ortho LC	VG
Mickenautsch and Yengopal, 2010[11]	*Am J Dent* 2008; **21**: 129																	x				
	Braz Dent J 2001; **12**: 35																	x				
	Caries Res 1997; **31**: 275																	x				
	J Dent 2002; **30**: 205																		x			
	Oper Dent 2002; **27**: 480																		x			
	J Dent Child 2007; **74**: 209																	x				
	Oper Dent 2008; **33**: 658																	x				
	Am JODO 1998; **114**: 668																				x	
	Ped Dent 2001; **23**: 255																				x	
	Caries Res 2008; **42**: 369																	x				
	Oper Dent 2003; **28**: 765																	x				
	Caries Res 2001; **35**: 200																	x				
	Am JODO 2004; **125**: 36																				x	
Mickenautsch and Yengopal, 2011[12]	*BDJ* 1991; **190**: 177				x																	
	Swed Dent J 1992; **16**: 81										x											
	Caries Res 2002; **30**: 437					x				x												
	Caries Res 2003; **37**: 246							x														
	CDOE 2007; **35**: 207					x				x												
	J CPD 2009; **34**: 53									x												
	Caries Res 2001; **35**: 90							x														
	IDJ 2004; **54**: 42					x				x												
	Caries Res 1992; **26**: 315						x															
	JDR 1997; **76**: 387				x																	
Mickenautsch *et al* 2010[13]	*J Dent* 2004; **32**: 285				x											x						
	Oper Dent 1999; **24**: 9				x											x						
	IJPD 2003; **13**: 2							x										x				
	[*OperDent* 2002; **27**: 430]				[x]													[x]				
Yengopal and Mickenautsch, 2011[14]	*Am JODO* 1999; **116**: 518																				x	
	J Dent 1998; **26**: 533																	x				
	AOS 2006; **64**: 334																	x				
	Oper Dent 2002; **27**: 430																	x				
	[*J Dent* 1996; **24**: 399]																[x]					
	Ped Dent 2000; **22**: 479																	x				
Hiiri *et al*, 2010[15]	*J Dent Child* 2001; **68**: 326																	x				
Yengopal and Mickenautsch, 2010[16]	*J DR* 2008; **75**: 134																	x				
	J CPD 2005; **29**: 133																	x				
	Am J Dent 1999; **12**: 59																			x		
	IJPD 1996; **6**: 235																x					
	J Dent 1996; **24**: 399																x					
	JADA 1996; **127**: 1508																		x			
Mickenautsch and Yengopal, 2011[17]	*J Fornos Med Ass* 2009; **108**: 844					x																
	J Dent Child 2009; **76**: 34									x												
	J Dent Child 1995; **62**: 108								x													
	CDOE 1995; **23**: 282				x																	
	BDJ 1996; **180**: 104								x													
	J Dent 1996; **24**: 275												x									
	IJPD 2008; **18**: 56								x													
	Caries Res 2006; **40**: 52									x												
	CDOE 2006; **34**: 36								x													

Table 1 continued

				C-GIC labels												RM-GIC labels						
Systematic review	**Trials Reviewed****	**ns**	**exp**	**3M ESPE**				**GC**			**Dentsply**		**BS**	**AS**	**IN**	**3M ESPE**			**GC**			**Vivadent**
				Ketac	**Ketac**	**Ketac**	**Ketac**	**Fuji**	**Fuji**	**Fuji**	**Chem**	**Chem**				**Photac**	**VB**	**VM**	**Fuji**	**Fuji**	**Fuji**	**VG**
				Cem	**Fil**	**Molar**	**Silver***	**II**	**III**	**IX**	**Fil**	**Flex**				**Fil**			**II LC**	**III LC**	**Ortho LC**	
	CDOE 1998; **26**: 21								x													
	Quint Int 1987; **18**: 707								x													
	CDOE 2001; **29**: 298								x													
	CDOE 1994; **22**: 21								x													
	BDJ 1981; **150**: 183													x								
	CDOE 1995; **23**: 25								x													
	Scand J DR 1990; **98**: 345								x													
Mickenautsch *et al*, 2010[18]	[*CDOE* 2007; **35**: 207]					[x]				[x]												
	JDR 2006; **85**: 622					x				x												
	Quint Int 2003; **34**: 31					x				x												
	JADA 2002; **133**: 744					x				x												
	[*IDJ* 2004; **54**: 42]					[x]				[x]												
	IJPD 2003; **13**: 172											x										
	[*Caries Res* 2002; **30**: 437]					[x]				[x]												
Yengopal *et al*, 2009[19]	*JADA* 1999; **130**: 1459																	x				
Mickenautsch *et al*, 2010[20]	*Dent Mater* 2003; **19**: 739																x					
	JADA 2001; **132**: 482																x					
	J Calif Dent Ass 2008; **36**: 51																					x
	JD 2001; **29**: 109																x	x				
	Am J Dent 2001; **15**: 41																x	x				
	J CPD 2006; **31**: 68																	x				
Millett *et al*, 2009[21]	*Eur J Orthod* 2003; **25**: 319			x																		
	Dissertation			x																		
	Am JODO 1997; **112**: 239			x															x			
	Latin Am J Orthod Pediatric Dent 2003; ns	x																				
	Am JODO 2001; 120: 49			x																		
	Eur J Orthod 1983; **5**: 307	x																				
	Br J Orthod 1991; **18**: 15		x																			
	Eur J Orthod 2005; **27**: 245														x							
	Total number of trials per label	2	1	4	5	7	1	3	10	9	1	1	1	1	1	2	6	21	4	1	4	1
	Duplications				1	3				3							1					

VB = Vitrebond; VG = Vivaglass; VM = Vitremer; BS = Baseline; AS = ASPA; IN = Intact; ns = Not specified; exp = Experimental material; * Cermet; [] = Trial in duplicate; **References of trials are recorded by their journal abbreviation, year of publication, volume number and number of first article page; CDOE = Community Dentistry and Oral Epidemiology; AOS = Acta Odontologica Scandinavica.

Table 1. Details of accepted systematic reviews: number of trials and represented GIC product labels.

in connection with the manufacturer name, and listed in order of the number of trials in which each product label was represented;

- The share of the different GIC products per manufacturer that were represented in the systematic review evidence was calculated (in %);
- Scope (eg Preventive dentistry; Restorative dentistry);
- Investigated clinical application (eg tooth restoration; fissure sealant);
- Clinical outcome (eg caries prevention; restoration survival);
- Conclusion in relation to the GIC product labels used in the reviewed clinical trials.

Results

Figure 1 provides information on the number of articles identified through the search strategy:

- A total of 1963 articles were identified by the PubMed database search;
- Of these, 1947 were excluded for being either trials or narrative reviews;

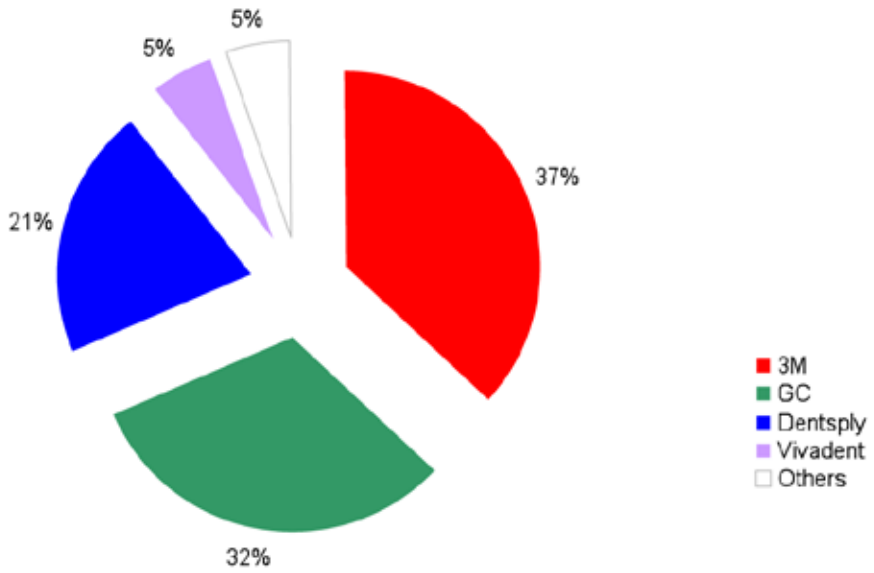

Figure 2. Glass-ionomer cement products represented by manufacturer in systematically reviewed trials (2009–2011).

Figure 3. Conventional glass-ionomer cement / branded label: Fuji IX (GC).

Figure 4. Resin-modified glass-ionomer cement/ branded label: Vitremer (3M ESPE).

Figure 5. Conventional glass-ionomer cement/ branded label: Ketac Molar (3M ESPE).

- Sixteen articles were included for further review;[11–26]
- From these 16, 11 were accepted[11–21] and 5 excluded.[22–26]

Reason for exclusion:

- Two systematic review articles lacked reported criteria for trial assessment in line with internal validity aspects (ie randomization, blinding);[22,23]
- Two original systematic review articles were excluded because their results had been revised by more recently published updates;[24,25]
- One review was excluded because it did not identify any trials acceptable in line with its set inclusion and exclusion criteria.[26]

The 11 accepted systematic reviews appraised evidence from a total of 70 trials. Eight of these trials were evaluated by more than one review (Table 1). Of the 70 trials:

- Three did not specify the name of the investigated GIC label or used an experimental material that was not yet available on the market.
- Sixty-seven trials reported on 12 C-GIC and 7 RM-GIC branded labels (n) from 4 manufacturers: Dentsply (n = 4); GC (n = 6); 3M (n = 7) and Vivadent (n = 1) (Table 1).
- The manufacturer of one C-GIC product, 'Intact', could not be specified.

A percentage distribution of GIC products by manufacturer, represented in the appraised trials, is shown in Figure 2. During the systematic literature search, no private label glass-ionomer products were identified. Branded labels of conventional GICs were represented in 44 of the 67 trials and those of resin-modified GICs in 39. Table 2 shows the number of trials per branded label. The conventional GIC products used in most trials were Fuji III (n = 10) and Fuji IX (n = 9, Figure 3). The resin-modified GIC product used in most trials was Vitremer (n = 21, Figure 4). Table 3 shows the systematic review conclusions in relation to the branded labels in terms of:

- Clinical material properties;[11–14]
- Clinical material applications with relevance to preventive dentistry;[15–17]
- Restorative dentistry[18–20] and orthodontics.[21]

Owing to limitations in the methodology of all the appraised trials, such as insufficient randomization procedure or high attrition, all systematic reviews concluded that further high-quality randomized control trials (RCT) were needed, in order to confirm (or disprove) the current trial findings. The state of current clinical knowledge, based on the reviewed trials, suggests association of branded GIC labels with the following systematic review conclusions:

- The C-GICs Fuji IX (GC) and Ketac Molar (3M ESPE – Figure 5) have a higher caries-preventive effect than that of amalgam;[12] a caries-preventive effect, as fissure sealant materials, similar to that of resin;[17] identical or in some cases even higher restoration survival rates in comparison to those of amalgam fillings;[19]
- The RM-GICs Vitremer and Vitrebond (3M ESPE – Figures 4 and 6) have a caries-preventive effect similar or superior to that of composite resin;[14] as fissure sealant materials, their caries-preventive effect is similar to that of resin;[16] when they were compared to calcium hydroxide cement, no differences in clinical pulp symptoms were found after 2 years;[20]
- The RM-GIC Fuji II LC (GC – Figure 7) has a higher reduction of demineralization[11] and the same caries-preventive effect as resin-based fissure sealants;[16]
- The RM-GIC Fuji Ortho LC (GC – Figure 8) provides a higher reduction of demineralization[11] than does composite resin and a similar or superior caries-

Figure 6. Resin-modified glass-ionomer cement/ branded label: Vitrebond (3M ESPE).

Figure 7. Resin-modified glass-ionomer cement/ branded label: Fuji II LC (GC).

Figure 8. Resin-modified glass-ionomer cement/ branded label: Fuji Ortho LC (GC).

GIC label	Manufacturer	Included in number of reviewed trials
Conventional glass-ionomer cement (C-GIC)		
Fuji III	GC	10
Fuji IX		9
Ketac Molar	3M ESPE	7
Ketac Fil		5
Ketac Cem		4
Fuji II	GC	3
Chem Fil	Dentsply	1
Chem Flex		1
Baseline		1
ASPA		1
Intact	ns	1
Ketac Silver*	3M ESPE	1
Resin-modified glass-ionomer cement (RM-GIC)		
Vitremer	3M ESPE	21
Vitrebond		6
Fuji II LC	GC	4
Fuji Ortho LC		4
Photac Fil	3M ESPE	2
Fuji III LC**	GC	1
Vivaglass	Vivadent	1
*Cermet; ** Experimental product. ns = Not specified		

Table 2. Glass-ionomer cement product labels represented in the clinical investigation of reviewed trials.

preventive effect.[14]

The association of further identified brand labels with systematic review conclusions is presented in Table 3.

Discussion

The systematic literature search did not discriminate between articles published in English and other languages; or between articles listed in major databases (PubMed, Cochrane Library) or other databases for open access journals (DOAJ, Open-J-Gate), as well as unpublished, so-called 'grey', literature (OpenSIGLE). However, only articles in English with PubMed listing were found. The systematic literature search was limited to articles published between 15 April 2009 and 14 April 2011. It has been suggested that, once the search date of a systematic review is older than one year, users should check for more recent trials on the same topic, to see whether new evidence has altered the findings of a given systematic review.[27] A further recommendation, in general, is to update the conclusions of a systematic review every two years.[27] For these reasons, conclusions from systematic review articles published before 15 April 2009 will not have included results from recent trials. Thus, only reviews published during the last two years were considered as still relevant and suited to the purpose of this article.

From the included articles, two were subsequently excluded because their results were outdated in light of more recent published versions,[24,25] that included the search results of the two original systematic reviews. Therefore, no information was lost due to article exclusion. One Cochrane review[26] did not identify trials in accordance with the selection criteria, so it did not include any information relevant to the aim of this article. The exclusion of two further systematic reviews,[22,23] owing to non-compliance with basic reporting criteria for systematic reviews (QUOROM), was justified, as neither assessed the internal validity of its accepted trials. Judgement of the internal validity of trials is an essential objective of a systematic review. The level of bias risk that is prevalent in a clinical trial defines its internal validity: bias or systematic error may cause overestimation of the true trial results. However, bias may be controlled through scientific methods, such as adequate randomization and blinding.[28] Without judgment of bias-controlling methods, a systematic review may risk carrying over any existing overestimation of the reviewed trial results.

It has to be noted that all trials appraised in the accepted systematic review

				Investigated product labels		Systematic review conclusions	
Scope	**Systematic review**	**Clinical application**	**Clinical outcome**	**C-GIC**	**RM-GIC**	**State of clinical knowledge based on reviewed trials**	**Need for further research to confirm current results**
Material research (Clinical material properties)	Mickenautsch and Yengopal, 2010[11]	Tooth restoration	Prevention of demineralization	–	Fuji II LC Fuji Ortho LC Vitremer	RM-GIC is associated with a higher reduction of demineralization in adjacent hard tooth tissue than composite resin without fluoride. No difference was found when RM-GIC was compared with fluoride-containing composite	Yes
	Mickenautsch and Yengopal, 2011[12]		Recurrent caries prevention	Fuji IX Fuji II Ketac Fil Ketac Molar Ketac Silver* Chem Fil	–	C-GIC has a higher caries-preventive effect in comparison to amalgam for restorations in permanent teeth. No difference was found for restorations in the primary dentition	Yes
	Mickenautsch *et al*, 2010[13]		Caries prevention	Fuji II Ketac Fil	Vitremer Photac Fil	No difference in the caries preventive effect between C-GIC and RM-GIC	Yes
	Yengopal and Mickenautsch, 2011[14]	Tooth restoration; Orthodontic bracket bonding	Caries prevention	–	Fuji Ortho LC Vitremer Vitrebond	Results showed no difference between the materials or indicated that RM-GIC has a superior caries-preventive effect when compared to composite resin	Yes
Preventive dentistry	Hiiri *et al*, 2010[15]	Fissure sealant	Prevention of pit and fissure caries	–	Vitremer	Dental sealants reduce more tooth decay in the grooves of posterior teeth in children than fluoride varnish application	Yes
	Yengopal and Mickenautsch, 2010[16]			–	Fuji II LC Fuji III LC** Vitremer Vitrebond	RM-GIC is as effective as resin-based fissure sealants to protect against caries	Yes
	Mickenautsch and Yengopal, 2011[17]			Fuji IX Fuji III Ketac Fil Ketac Molar Baseline ASPA	–	C-GIC is as effective as resin-based fissure sealants to protect against caries	Yes
Restorative dentistry	Mickenautsch *et al*, 2010[18]	Atraumatic restorative treatment (ART)	Restoration survival	Fuji IX Ketac Molar Chem Flex	–	Same or higher survival rate of ART restorations in permanent teeth (Class I, V and II) when compared to amalgam	Yes
	Yengopal *et al*, 2009[19]	Restorative treatment of primary teeth	Restoration survival	–	Vitremer	No difference when compared to amalgam	Yes
	Mickenautsch *et al*, 2010[20]	Restorative treatment of deep tooth cavity	Pulp response	–	Vitremer Vitrebond Vivaglass	No difference in clinically identifiable pulp symptoms after two years when compared with calcium-hydroxide cement	Yes
Ortho-dontics	Millett *et al*, 2009[21]	Bracket bonding	Debonding rate; Caries prevention	Ketac Cem	Fuji II LC	Insufficient high-quality evidence with regard to the most effective adhesive for attaching orthodontic bands to molar teeth	Yes

*Cermet; **Experimental material. C-GIC = Conventional chemically curing glass-ionomer cement; RM-GIC = Resin-modified, light-cured glass-ionomer cement.

Table 3. Topics and conclusions of systematic reviews related to glass-ionomer cement product labels.

investigated the dental material categories on which the labels are based but did not investigate the labels as such. Different labels in the same category, eg high-viscosity conventional GIC: Ketac Molar and Fuji IX, may differ from each other to some extent. It may be questioned whether such difference would translate into any difference in clinical efficacy. Such consideration is supported by the stance taken in EU guidelines on medical devices,[29] which recognizes a degree of diversity between different labels in the same or similar medical device categories but requires manufacturers to base their product labels only on clinical evidence confirming efficacy of the underlying medical device category, and not on clinical evidence confirming the efficacy of the specific labelled product.[29]

Although only indirect association can be made between the systematic review conclusions and the identified branded labels, it needs to be emphasized that the labels, listed in Table 2, are the only ones of all the GIC products currently on the market that have not merely been subjected to scientific clinical investigation in trials: during the last two years the results of these investigations have been further scrutinized through systematic evidence appraisal.

Conclusion

Based on a systematic literature search, this article has identified glass-ionomer cement products in relation to conclusions of systematic reviews published in peer-reviewed journals during the last two years.

- The conventional and resin-modified glass-ionomer cements that were used in most trials were marketed by GC and 3M ESPE, respectively.
- The conventional GICs used in most of the reviewed trials were Fuji III and Fuji IX.
- Vitremer was the most commonly used resin-modified GIC.

The current results of the reviewed trials suggest beneficial effects of GIC in preventive and restorative dentistry. However, more trials of higher internal validity are needed in order to confirm (or disprove) the current results. Only GIC products of branded labels and none of private labels were identified. This suggests that private label GIC products have little or no research back-up.

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