## **RESTORATIVE DENTISTR**



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## Systematic review on highly viscous glass-ionomer cement/resin coating restorations (Part I): Do they merge Minamata Convention and minimum intervention dentistry?

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Background: With the Minamata Convention the use of mercury will be phased down, and this undoubtedly will have an effect on dental treatment regimens and economic resources. Composite resin restorations are considered viable alternatives to amalgam fillings; however, these will not be covered completely by health insurance systems in many countries. Recently, a high-viscosity glass-ionomer cement (hvGIC) processed with a resinous coating (RC) has been introduced, and has been marketed as a restorative material in load-bearing Class I cavities (and in Class II cavities with limited size), thus serving as a possible alternative to amalgam fillings. Objective: To evaluate the literature on this treatment approach, and to focus particularly on the clinical performance of the hvGIC/RC combination. Search Strategy: The Cochrane Library as well as Ebsco, Embase, PubMed, and Scopus databases were screened. Moreover, relevant abstracts published

with dental meetings were reviewed. **Selection Criteria:** All available randomized clinical trials focusing on the hvGlC/RC approach (published either as full-texts or abstracts until June 2016) were selected. Moreover, single-group studies using hvGlC/RC were included. **Data Collection and Analysis:** Screening of titles and abstracts, data extraction, and quality assessments of full-texts according to Oxford scoring were performed. **Results:** Regarding failure rates, minor differences between hvGlC/RC and GlC or composite resins as comparators could be observed in seven clinical studies. The hvGlC/RC combination showed high survival rates (with only few catastrophic failures) of up to 6 years. **Conclusion:** Class I retention rates of hvGlC/RC seem promising, but further high-quality clinical studies are clearly warranted. (*Quintessence Int 2016;47: 813–823; doi: 10.3290/j.qi.a36884*)

Key words: amalgam, Class I and Class II cavities, clinical trial, composite resin, high-viscosity glass-ionomer cement, Minamata Convention, minimum intervention dentistry, resin coating

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Since its first dental application almost two centuries ago, silver/mercury amalgam has been an appropriate and most successful restorative filling material, offering

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a good clinical performance up to the present day. However, current efforts such as the Minamata Convention provide for global regulation and the ultimate cessation of mercury processing, and, with this in mind, a so-called phase-down of dental amalgam appears to be on the agenda.<sup>1</sup> This is not the only motion in the current debate: Modern dentistry strives for minimally invasive treatment approaches,<sup>2,3</sup> and this raises the question of what filling materials offer potential alternatives to amalgam restorations in the long run, thus paving the way into a mercury-free future.<sup>2,4,5</sup>

Up to now, amalgam has played an important role in dental care worldwide, in particular because of its beneficial physical properties (eg, ease of processing, high wear resistance, and good marginal adaptation).<sup>6</sup> Under certain conditions (and in many areas of the world), the use of amalgam undoubtedly remains advisable if placed with due care and attention to detail;<sup>4</sup> this also has been suggested by the updated SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) report: "Dental amalgam is an effective restorative material and is a material of choice for specific restorations."7 At least from a functional point of view, there are no objections with respect to amalgam fillings, and these restorations may serve well for many years (Fig 1); even an acute individual health risk to the human body has not been proven so far.7 Nevertheless, the dental use of amalgam is still a matter of discussion, and this debate is driven by its mercury content of about 50% on the one hand, while on the other hand esthetic and in particular environmental aspects have become increasingly important in recent years.

## **MERCURY: A GLOBAL PROBLEM**

To the present day, various measures were intended to lower any possible emotional and environmental burden, and tried to minimize or even stop the corresponding problems. While patients reject the silvery-gray amalgam fillings mostly for esthetic reasons (and demand tooth-colored restorations), environmental issues have, up to recently, not influenced the choice of restorative materials decisively.<sup>24,8</sup> There have been continual pressures from recent environmental developments: since 2009, the World Health Organization (WHO) has been discussing a ban on mercury, and even in the European Union (EU) and the World Dental Federation (FDI) the subject has been a matter of debate for some time now.<sup>9,10</sup> It should be borne in mind that dentists used approximately 240 to 300 metric tons of mercury as an ingredient in dental amalgam worldwide in 2005.<sup>11</sup>

In particular, the disposal of dental mercury residues has always been part of the European agenda. In many member states, the use of amalgam separators has been mandatory for many years now, and appropriate systems have been established;<sup>12</sup> however, this does not apply to the entire EU.<sup>13</sup> Besides that, there are differences within the EU member states in terms of concrete measures, although the EU Commission has been discussing whether to interdict the use of dental amalgam completely for many years now. Notwithstanding, Sweden has applied a mercury ban since 2009, while in Norway, a retreat in special situations was issued in 2008, which culminated in a complete renunciation in 2011;<sup>12</sup> evidence has been found that the quality of dental care does not necessarily deteriorate by avoiding mercury-containing restorations.<sup>12</sup> Both in Austria and in Germany, a restricted use (with respect to pregnancy, lactation, childhood, renal disease, and allergy) has been established some 20 years ago.<sup>14,15</sup> Moreover, the Japanese authorities addressed the mercury problem early. Nowadays, amalgam is used for less than 4% of restorations nationwide, and, in addition, 93% of dental schools have been reported to teach the use of alternative materials in preference to amalgam.<sup>13</sup> Overall, however, the accumulation of mercury in the environment continues to be a global challenge.

## **MINAMATA: A GLOBAL SOLUTION**

New impetus to environmental issues was given through a global agreement, initiated by the United Nations Environment Programme (UNEP),<sup>11</sup> and supported by the WHO,<sup>16</sup> pursuing the global reduction of

mercury exposure: The so-called Minamata Convention, adopted in Japan in 2013, aims at reducing the use and the emission of mercury worldwide to contain the environmental pollution and to prevent possible harm to the population.<sup>1</sup> Named after the Japanese Minamata Bay (where there were 2,000 deaths as a result of the perpetual consumption of contaminated fish by the local population in the 1950s), the Convention includes inter alia the ban on new mercury mines, control measures for air emissions, international regulations of gold mining, as well as a gradual phase-down of dental amalgam.<sup>1</sup> The recently adopted Minamata Convention will enter into force when 50 countries have ratified this agreement. Currently, the treaty has been signed by 128 nations, with 28 of these having ratified the Convention (including the United States as the first and Switzerland, Mali, and Botswana as the most recent ratifying states as of June 2016).<sup>1</sup>

From 2020 on, in accordance with the Convention, no more mercury should be used in a wide range of products – but how does this work? A look at other industries brings clarity: For instance, it is said that mercury in sphygmomanometers and thermometers can only disappear when there are accurate, reliable, and affordable alternatives.<sup>11</sup> This also applies to dentistry, where switching to filling alternatives should have no impact on the general quality of dental care.<sup>9</sup>

Therefore, it is considered consistent that the strategies considering the Minamata Convention were aligned globally and it was agreed to set future priorities on prevention, the research on alternative dental materials, and to an application in conformity with directives.<sup>17</sup> However, the implementation of modern therapeutic approaches puts high expectations on the materials; besides easy processing, low abrasion, and a dense adhesion, these new materials should have low shrinkage values, acceptable appearance, and good color retention. In addition, there is a broad consensus in the dental community that the historical concept of "drill and fill" of macroretentive, tissue-sacrificing cavities is obsolete;<sup>4</sup> instead, a timely and generally accepted "heal and seal" philosophy is considered imperative.<sup>5</sup> Against the backdrop of the current orien-



**Fig 1a** Bitewing radiograph (section of maxilla) revealing a 25-year-old, three-surface restoration of the maxillary right first molar in a 51-year-old woman. No signs of further proximal caries or increased attachment loss visible, thus indicating a low caries risk, along with an adequate oral hygiene.



**Fig 1b** Corresponding clinical aspect of the amalgam restoration (mod), placed in 1991 by one of the authors (AMK) using a dispersed phase, low mercury, high copper, and palladium-enriched amalgam (Valiant PhD; lvoclar Vivadent). Marginal discrepancies, advanced wear, tarnish, and corrosive surface pitting are evident, but replacement would not seem necessary even after the comparatively long time of service.

tation on patient-centered, prevention-oriented, and minimally invasive approaches, the suitability of amalgam as a contemporary filling material would seem questionable, at least in cases of small cavities not referring to re-dentistry.

Undoubtedly, composite resins have become established as all-purpose direct restorative materials both for anterior and posterior teeth, since these materials offer long-term survival rates even under function, insolubility and acceptable biocompatibility if adequately polymerized, as well as a great choice of different shades and opacities (thus leading to highly esthetic results and versatile possibilities).<sup>18</sup> In contrast, polymerization shrinkage and the need for a long-term waterproof seal between material and enamel or dentin are considered major shortcomings; notwithstanding, restoring a tooth with composite resins is successfully possible, but remains technically sensitive, and calls for well-controlled conditions and impeccable clinical skills. Thus, from an economic perspective, composite resins will hardly ever be an adequate alternative to dental amalgam, at least in several countries.

For economically underprivileged patients, this currently leaves only glass-ionomer cements (GICs) as possible amalgam alternatives in dedicated cases of direct restorations. However, glass ionomers have traditionally been regarded as clinically inferior to amalgam, and this has been supposed to be based mainly on laboratory studies showing poor mechanical properties.<sup>19</sup> Additionally, this formerly reserved attitude was driven by expert opinions and narrative reviews focusing on non-controlled longitudinal studies only.<sup>20</sup> Interestingly enough, recent analyses of systematic reviews have shown that highly viscous glass-ionomer cement [hvGIC] restorations are clearly not inferior to silver/mercury amalgam fillings, and may offer an alternative to the alloy, even in small but load-bearing cavities of permanent teeth.<sup>21</sup> This might even come true for previously introduced hvGIC (Fuji IX GP extra/EQUIA Fil; GC), being processed with light-cured nanofilled resin top coats [RC] (G-Coat Plus/EQUIA Coat; GC), and revealing increased physical properties; such a material combination has been marketed since 2007 (and is currently known as EQUIA Fil restorative concept).<sup>22</sup> Up to now, however, no concluding overview on this material combination is available from the accessible literature. Since analysis of clinical data requires documentation, this systematic review reports on the use of this hvGIC/RC approach as a possible alternative for other direct restorations (such as amalgam). The aim was to present the state of knowledge on this currently used hvGIC/RC combination in Class I and II cavities.

## METHOD AND MATERIALS

## **Protocol and generation**

The authors framed an answerable and investigable research question to the established PICOT<sup>23</sup> format: "For adult patients suffering from proximal or occlusal caries

in posterior teeth (Problem/Patient), will a restorative treatment based on hvGIC/RC (Intervention, in particular using EQUIA Fil/EQUIA Coat) as compared to a composite or amalgam filling or to a GIC restoration (Control/ Comparison) result in a comparable clinical performance (Outcome) in the medium and long term (Time)?" To allow for comparison we primarily adhered to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines;<sup>24</sup> however, in case of any identified risk of bias, studies were not excluded in this review to collate all qualitatively relevant information on the clinical performance of hvGIC/RC.

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# Eligibility criteria for considering studies for this review

#### Types of studies

All clinical trials investigating and reporting the aforementioned approach of using hvGIC processed with a resinous coating (RC) using conventional preparation techniques in premolars and molars were selected.

## Participants

A quorum of at least 20 participants (subjects of any age in need of a posterior restoration, due to caries or loss of restoration) was present at each study.

## Types of intervention

Class I and Class II cavities in premolars and molars were treated using hvGIC, along with a RC.

## Types of comparators

Silver amalgam, composite resins, or glass ionomers used in Class I and Class II cavities in premolars and molars were searched and compared to the hvGIC/RC approach.

## Types of outcome measures

All measurement results were primarily based on clinical performance, with modified US Public Health Service (USPHS) criteria including anatomical shape, surface texture, color match, and marginal discolorations as adopted criteria. Additionally, marginal adaptation, retention, and secondary caries were in the focus of interest.

## Data sources and search methods for identification of studies

The electronic data search was executed for studies evaluating their restorations for a minimum period of 6 months, and was performed independently by two authors (AMK, GG) on the Cochrane Library, and Ebsco, Embase, PubMed, and Scopus. As basic search terms "glass ionomer cements", "EQUIA" and "resin coat" as well as "composite resin" or "amalgam" were used (and adapted for the respective databases). After all abstracts were screened, relevant full-texts were obtained. Moreover, to revise for possible additional papers, the reference lists of the identified and relevant papers on the subject were reviewed. The main aim was to screen for randomized clinical trials (RCTs); thus, prospective studies including control groups focusing on the clinical performance were considered primarily relevant for the current systematic evaluation. However, interventional or retrospective studies were not excluded in case of missing identifiable or appropriate RCTs. Additionally to the search of databases, congress abstract books were screened for further clinical trials in progress; these were included in the present paper for completeness reasons (but were not eligible for further quantitative evaluation, due to their limited information, and their inherent missing quality of reporting). Last, reference lists of included reports were screened, and hand-searching for suitable trials completed the identification process.

## Screening process

Any possible dissensions between the authors were consented by mutual agreement after discussion. All relevant titles and abstracts where screened and searched for clinical trials focusing on the hvGIC/RC approach. Full-texts were obtained and analyzed accurately including titles and abstracts, and identified references were considered eligible for inclusion if the following inclusion criteria were given:

- full-texts of clinical trials, in particular randomized controlled trials
- study focus relevant to PICOT question
- head-to-head comparison of hvGIC/RC to amalgam or composite resin or GIC

- Class I or Class II restorations using conventional preparation techniques
- longest follow-up reported
- trials reported in English (either full-texts or abstracts until June 2016).

Exclusion criteria were review papers and reported clinical studies not using the combination of hvGIC/RC in Class I/ Class II cavities. Case reports, technical reports, laboratory studies, or trials focusing on Atraumatic Restorative Techniques (ART) were not included for the main objective, but were considered for explanation of observed effects.

## Data collection process and analysis

Publications were reviewed for relevance and data were extracted. All accepted studies were listed to allow for comparison within the studies, with regard to study design, used materials, number of participants, duration of the clinical trial, and clinical performance of the restorations.

## Quality assessment and synthesis of results

To limit the risk of bias and any possible distortion only studies matching all assigned criteria were added, and all others were discarded. To analyze the outcome and to allow for comparison of the full-text RCTs, the Oxford quality scoring system was used for evaluation by all authors (AMK, GG, MW, KG). Studies were scored according to the methodologic features of clinical trials (randomization, double-blinding, and accountability of all patients, including withdrawals), with added points for a "yes" answer to each of the five items, and deducted points for a "no" answer to two items (if randomization and blinding inappropriately described). This three-feature brevity gives the least responder burden for an overall score of up to five points, meaning the best possible result and verifying that the quality in category comparability of the study is high and the risk of bias is low; scoring 0 points means poor quality and high risk of bias.

Finally, study characteristics and outcomes of clinical trials were compared to allow for a clear statement regarding any possible recommendations of the hvGlC/ RC approach.

## RESULTS

## Study selection and characteristics of excluded studies

The PubMed search resulted in 61 clinical reports, while Embase provided 19 publications; retrieval via Scopus also led to 19 articles, and the search at Ebsco resulted in five reports. The Cochrane Library was also screened, and two articles were found. Furthermore, 16 abstracts (along with one hand-searched paper) reporting interim results (and referring to three RCTs<sup>25-27</sup> and one single-group<sup>22</sup> study as full-texts) and to two handsearched papers reporting on single-group studies<sup>28,29</sup> were identified, while three additional abstracts reporting an RCT in progress<sup>29</sup> (not published as full reports up to June 2016) could be found, thus resulting in a total of 125 papers and abstracts. After review of all fulltexts and abstracts, 99 documents were excluded. The most common reasons for exclusion were:

- use of composite or GIC (without resin coating) only
- study not focused to PICOT question
- study not referring to conventional Class I or Class II cavities (or reporting on ART).

After subordinating (but not completely excluding) 18 records focusing on interim or laboratory results<sup>31-47</sup> (and thus also refusing duplicate or interim full reports<sup>48</sup> referring to the same studies), a total of six full-texts<sup>22,25-29</sup> and one abstract<sup>30</sup> representing the longest observation periods of seven independent trials were identified and considered for further analysis. The study selection process is summarized in Fig 2.

## **Quality of included studies**

Screening as well as data extraction and assessment of full reports according to three Oxford criteria (1 – randomization; 2 – blinding; 3 – reported analysis of dropout rates) resulted in three RCTs<sup>25-27</sup> considered for evaluation, and two of those were rated as low-quality reports (with high risk of bias). Results of the Oxford scoring are given in Table 1. Due to the low number of (multi-center) single-group studies<sup>22,28,29</sup> and fully reported RCTs<sup>25-27</sup> (as well as due to the non-fully reported RCT<sup>30</sup>), no meta-analysis was advisable.

## Compilation, characteristics, and outcome of included studies

In general, durability, resilience, and marginal adaptation of the hvGIC/RC combination was verified in all consulted controlled and randomized studies. This outcome was reported by different study groups over various follow-up periods (ranging from 6 months<sup>31</sup> to 6 years<sup>30,38</sup>). A summary of all relevant studies (full-texts and abstracts) included in the present paper is shown in Table 2.

#### Failure rates with Class I cavities

In total, the seven studies reported on some 500 Class I cavities treated. All studies except one<sup>31</sup> (including the single-group studies)<sup>22,28,29</sup> documented high survival rates of up to 100%,<sup>25,26,40</sup> for the hvGIC/RC approach, even after 5<sup>37</sup> and 6 years.<sup>30,38</sup> The included RCTs compared the hvGIC/RC combination either to glass ionomers,<sup>30,31</sup> or to composite resins,<sup>25,26</sup> and these comparisons did not reveal any significant differences after 2,<sup>40</sup> 3,<sup>25</sup> or after up to 5 years;<sup>26,37</sup> however, significant differences were observed between hvGIC/RC and GIC<sup>30</sup> as well as between hvGIC/RC and composite resin<sup>38</sup> after 6 years.

#### Failure rates with Class II cavities

All in all, some 800 Class II cavities were studied in six (of the seven studies). As with the Class I restorations, survival rates were high in all studies, and ranged to some 90% after 4 years.<sup>26,29,47</sup> Again, the included RCTs did not reveal any significant differences between hvGIC/RC restorations and the respective control groups (GIC<sup>27,40</sup> or composite resin<sup>26</sup>), with even fewer failures in the follow-up intervals for pooled Class I and Class II fillings.<sup>47</sup> However, there was a clear tendency for breakdown of large Class II restorations from their marginal ridges leading to replacement needs, and this was observed with other reports as well.<sup>22,30,40,44,47,50</sup>

#### Secondary caries

Only one report noted some failures due to secondary caries,<sup>25</sup> and this was not observed with the other studies.<sup>22,26,28,29,40,47</sup>



Fig 2 Inclusion criteria for hvGIC/RC studies analyzed in the present review.

#### Table 1 Quality assessment of RCTs according to the Oxford scoring system

	Study		
Parameter	Diem et al <sup>25</sup>	Gurgan et al <sup>26</sup>	Klinke et al <sup>27</sup>
Study described as random? (yes, +1; no, 0)	0	1	1
Method of randomization described and appropriate? (yes, $+1$ ; no, $-1$ )	NA	1	1
Study described as double-blind? (yes, +1; no, 0)	0	0	1
Method of double-blinding described and appropriate? (yes, $+1$ ; no, $-1$ )	NA	NA	1
Description of withdrawals and dropouts? (yes, +1; no, 0)	1	1	0
Total points	1	3	4
Quality of study	Low range of quality	High range of quality	High range of quality
Risk of bias	High	Low	Low

NA, not applicable.



Table 2         Compilation of studies having evaluated the clinical performance of highly viscous GIC with resin coating (hvGIC/RC)						
Year	Study	Study type/ follow-up time	Publication type	Comparison (test gro group)	oup vs control	Patients/teeth included
2010	Gurgan et al32	RCT/6 mo	Abstract	EQUIA Fil (GC)	Gradia Direct (GC)	26/60
2011	Gurgan et al <sup>33</sup>	RCT/12 mo	Abstract	EQUIA Fil (GC)	Gradia Direct (GC)	26/60
2012	Gurgan et al <sup>34</sup>	RCT/24 mo	Abstract	EQUIA Fil (GC)	Gradia Direct (GC)	26/60
2012	Gurgan et al <sup>35</sup>	24 mo (REM study)	Abstract	EQUIA Fil (GC)	Gradia Direct (GC)	NS//NS
2013	Gurgan et al49	RCT/24 mo	Full-text	EQUIA Fil (GC)	Gradia Direct (GC)	30/60
2013	Gurgan et al <sup>36</sup>	RCT/36 mo	Abstract	EQUIA Fil (GC)	Gradia Direct (GC)	26/60
2015	Gurgan et al <sup>26</sup>	RCT/48 mo	Full-text	EQUIA Fil (GC)	Gradia Direct (GC)	59/140 (80 Class I/60 Class II)
2014	Gurgan et al <sup>37</sup>	RCT/60 mo	Abstract	EQUIA Fil (GC)	Gradia Direct (GC)	59/140 (80 Class I/60 Class II)
2015	Gurgan <sup>38</sup>	RCT/72 mo	Abstract/lecture	EQUIA Fil (GC)	Gradia Direct (GC)	59/140 (80 Class I/60 Class II)
2010	Türkün and Kanik <sup>39</sup>	RCT/18 mo	Abstract	Fuji IX GP extra (GC)	Riva self cure (SDI, Victoria, Australia)	54/252
2011	Kanik and Türkün <sup>40</sup>	RCT/24 mo	Abstract	Fuji IX GP extra (GC)	Riva self cure (SDI)	54/256
2015	Türkün and Kanik <sup>30</sup>	RCT/60 mo	Abstract	Fuji IX GP extra (EQUIA Fil; GC)	Riva self cure (SDI)	54/252
2011	Basso et al <sup>41</sup>	Single-group study/18 mo (mean)	Abstract	EQUIA Fil (GC)	No control	245/378
2013	Basso et al42	Single-group study/36 mo (mean)	Abstract	EQUIA Fil (GC)	No control	155/288
2013	Basso et al43	Single-group study/40 mo (mean)	Abstract	EQUIA Fil (GC)	No control	232/380
2014	Basso et al44	Single-group study/48 mo	Abstract	EQUIA Fil (GC)	No control	202/304
2015	Basso et al <sup>29</sup>	Single-group study/48 mo	Full-text	EQUIA Fil (GC)	No control	202/304
2011	Khandelwal et al <sup>45</sup>	Retrospective (single-group)/24 mo (median)	Abstract	EQUIA Fil (GC)	No control	43/151
2011	Friedl et al <sup>22</sup>	Retrospective (single-group)/24 mo (median)	Full-text	EQUIA Fil (GC)	No control	43/151
2013	Miletić et al <sup>28</sup>	Single-group study/12 mo	Full-text	EQUIA Fil (GC)	No control	27/45
2013	Diem et al <sup>25</sup>	RCT/36 mo	Full-text	Fuji IX GP extra (EQUIA Fil; GC)	Solare (GC)	91/254
2013	Klinke et al <sup>46</sup>	RCT/24 mo	Abstract	EQUIA Fil (GC)	Fuji IX GP fast (GC)	NS/973
2015	Klinke et al47	RCT/48 mo	Abstract	EQUIA Fil (GC)	Fuji IX GP fast (GC)	NS/1,001
2015	Klinke <sup>31</sup>	RCT/48 mo	Abstract	EQUIA Fil (GC)	Fuji IX GP fast (GC)	643/1,001
2015	Klinke et al <sup>47,48</sup>	RCT/48 mo	Abstract/Poster	EQUIA Fil (GC)	Fuji IX GP fast (GC)	NS/1,002
2016	Klinke et al <sup>27,54</sup>	RCT/48 mo	Full-text	EQUIA Fil (GC)	Fuji IX GP fast (GC)	643/1,001

NS, not specified.

## Abrasion resistance and wear

No significant differences concerning wear were reported between hvGIC/RC and composite resins,<sup>25,49</sup> even after 4 and 5 years of service.<sup>26,37</sup> However, a considerable number of hvGIC/RC restorations revealed volume loss, and this was higher with multi-surface

fillings, along with a visible and perceptible roughness increase.<sup>22</sup>

#### Chipping of material

Small fractures of margins/chipping of edges (< 1 mm, and considered polishable) were reported as

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Patients/teeth with fol- low-up	Cavity design	Outcome	Survival rates of hvGIC/RC
25/58	Class II	No difference between materials	Class II: 100%
25/58	Class II	No difference between materials	Class II: 100%
23/53	Class II	No difference between materials	Class II: 100%
NS//NS (2 per patient)	Class I	No difference between materials	NS
NS//NS	Class I	No difference between materials	Class I: 100%
23/53	Class II	No difference between materials	Class II: 96.2%
52/126 (76 Class I/50 Class II)	Class I and II	No difference between materials	Class I: 100%; Class II: 92.3%
52/126 (76 Class I/50 Class II)	Class I and II	Significant differences between Class I and Class II	Class I: 100%; Class II: 92.3%
47/115 (70 Class I/45 Class II)	Class I and II	No difference between materials	Class I: 100%; Class II: 100% (compare loss after 4 years)
50/NS	Class I and II	No difference between both GIC	Class I: 100%; Class II: 100%
52/248	Class I and II	No difference between materials	Class I: 100%; Class II: NS ("some" losses)
37/NS	Class I and II	EQUIA Fil significantly better than Riva	Class I: NS; Class II: NS
NS/374	Class I, II, and V	NS	Class I: 100%; Class II: 97.3%; Class V: 95%
NS/283 (78 Class I/137 Class II)	Class I, II, and V	NS	In general: 96.6%
NS/319 (83 Class I/164 Class II)	Class I, II, and V	NS	In general: 95.6%
202/304 (82 Class I/150 Class II)	Class I, II, and V	High number of failures with Class II	Class I: 98.8%; Class II: 84.0%; Class V: 86.1%
202/304 (82 Class I/150 Class II)	Class I, II, and V	NS	Class I: 98.8%; Class II: 90.0%; Class V: 86.1%
43/151 (26 Class I/125 Class II)	Class I and II	NS	Class I: 100%; Class II: 100%
43/151 (26 Class I/125 Class II)	Class I and II	Performance higher with small Class II cavities	Class I: 100%; Class II: 92.8%
27/45 (23 Class I/22 Class II)	Class I and II	NS	Class I: 100%; Class II: 100%
NS/198	Class I	No difference between materials	Class I: 100%
NS/644 complying with the study protocol (367 with the manufacturer's indications)	Class I and II	No differences between EQUIA and GIC	Class I: 96.3%; Class II: 96.1%
NS/772 (302 Class I/470 Class II)	Class I and II	No difference between materials	Class I: 100%; Class II: 98.5%
NS//NS	Class I and II	Better overall performance with EQUIA	High percentage of unsatisfactory/poor Class II restor- ations
NS/97 with annual follow-up	Class I and II	NS	High loss to follow-up
510/782 (503 within the manufacturer's indications)	Class I and II	No significant difference between both materials within 4 y	High percentage of unsatisfactory/poor Class II restorations (3 surfaces worse than 2 surfaces)

constantly increasing with time,41-43 with 39 (out of 271) restorations in need of minor interventions not leading to replacement after 4 years,<sup>44</sup> but contributing to a decrease of the overall integrity rate of the hvGIC/RC restorations.<sup>29</sup> This was corroborated by other trials reporting on significantly increasing marginal disintegration with time,25,30,37 or with cavity extension.22

## Color match

Although not considered a primary outcome, color match of the hvGIC/RC approach was satisfactory after

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up to 4 years;<sup>25,26,28</sup> even if color match was not the primary intention, color was considered satisfactory with some 30% of restorations.<sup>22</sup>

#### Synthesis of results

Up to June 2016, three full-text RCTs (comparing hvGIC/RC to composite resins with Class I<sup>25</sup> and Class I/ Il cavities;<sup>26,27</sup> all of them with some risk of bias) have been published, while another further RCT (focusing on comparisons between hvGIC/RC and GIC) is still in progress, and has not been fully published yet.<sup>30</sup> No trials reporting on comparisons between hvGIC/RC and amalgam have been published so far. From the available literature (including three single-group studies<sup>22,28,29</sup>), the hvGIC/RC approach would seem promising with regard to retention rates, abrasion resistance, and clinical fracture toughness, at least with regards to Class I and small Class II cavities in the short and medium term, where no catastrophic failures have been documented. However, it should be emphasized that a considerable number of Class II restorations was lost in one of the RCTs,<sup>50</sup> along with a higher number of losses in the control group. Thus, risk of failure was higher with Class II restorations (if compared to one-surface fillings), in particular if manufacturer's recommendations were not followed (and cavity size was overextended).50

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