ARE GLASS CARBOMER SEALANTS MORE EFFICIENT IN PREVENTING CARIOUS LESIONS IN CHILDREN'S PERMANENT MOLARS WHEN COMPARED TO OTHER SEALANT MATERIALS? A SYSTEMATIC REVIEW AND META-ANALYSIS

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Palavras-chave: Selantes de Fóssulas e Fissuras. Cárie Dental. Revisão Sistemática.

RESUMO

Objetivo: Esta revisão sistemática foi realizada para avaliar a eficácia de selantes de fóssulas e fissuras em carbômero de vidro comparados a outros materiais seladores na prevenção de lesões cariosas em crianças e retenção em fóssulas e fissuras. **Fontes dos dados**: Este estudo incluiu apenas estudos clínicos randomizados que compararam selantes em carbômero de vidro com selantes em outros materiais em molares permanentes em crianças com um acompanhamento mínimo de 6 meses. Uma busca sistemática foi realizada nas bases de dados PubMed, Scopus, Web of Science, LILACS, BBO, Cochrane Library e literatura cinzenta. Resumos de IADR, registros de triagens clínicas não publicadas, bases de dissertações e teses também foram pesquisados. O risco de viés dos estudos foi avaliado por meio da ferramenta Cochrane e a qualidade da evidência com o GRADE. Metanálises foram realizadas com os estudos que permitiram a coleta de dados. **Síntese dos dados**: Um total de 1685 artigos foram identificados e 54 selecionados para revisão. Destes, 40 artigos foram excluídos depois da leitura do resumo e 8 foram incluídos na análise qualitativa e quantitativa. A prevalência de fóssulas e fissuras livres de cárie foi similar após 6 (p=0,77; I^2= 0%) e 12 meses (p=0,60; I^2= 0%) e qualidade da evidência foi considerada baixa; após 24 meses, os outros materiais tiveram melhor desempenho (p=0,30; I^2=7%) com evidência moderada. Não houve diferença nas taxas de retenção dos diferentes materiais após 6 (p<0,0001; I^2= 96%), 12 meses (p<0,0001; I^2= 99%), ou 24 meses (p<0,0001; I^2= 100%) de acompanhamento; a qualidade foi considerada muito baixa. **Conclusão**: Selantes de carbômero de vidro tem retenção similar aos outros materiais seladores utilizados. Em relação ao desenvolvimento de novas lesões de cárie, os outros materiais apresentaram melhor desempenho ao longo do tempo. Todavia, novos estudos clínicos devem ser desenvolvidos para corroborar estes achados, uma vez que há falta de qualidade na evidência obtida.

Keywords: Pit and Fissures Sealants. Dental Caries. Systematic Review. Glass Carbomer Cement.

ABSTRACT

Objective: This systematic review was performed to evaluate the efficacy of glass carbomer when compared with other sealant materials in preventing carious lesions in children and retention in pit and fissures. **Sources of data**: The paper included only randomized clinical trials that compared pit and fissure sealants with glass carbomer and other sealant materials in children's permanent molars with at least six-month follow-up. A systematic search was performed in PubMed, Scopus, Web of Science, LILACS, BBO, Cochrane Library and Grey literature (December 2020/January 2021). The risk of bias tool from the Cochrane Collaboration was used for quality assessment of the studies and GRADE approach for the quality of the evidence. Meta-analysis was performed on studies from which data could be achieved. **Synthesis of data**: A total of 1685 papers were identified, 54 were selected for review. From these, 40 articles were excluded after the reading of the abstract and 14 articles were put aside for assessment. Eight papers were included in qualitative and quantitative synthesis. The prevalence of caries-free pit and fissures did not show differences after six (p=0.77; I^2= 0%) or 12 months (p=0.60; I^2= 0%) and the quality of the evidence was judged as low; after 24 months, other sealant materials performed better (p=0.30; I^2=7%) and the quality as moderate. There were no differences in the retention rates of the different materials after six-month (p<0.0001; I^2= 96%), 12-month follow-up (p<0.0001; I^2= 99%) and 24 months (p<0.00001; I^2= 100%); the quality of the evidence was considered very low. **Conclusion**: Glass carbomer sealants have a similar performance to other sealant materials when retention is considered. For the development of new carious lesions, other sealant materials performed better over time. However, new clinical trials are needed to corroborate these findings since it still lacks quality to the evidence raised.

Submitted: August 21, 2020
Modification: February 01, 2021
Accepted: February 17, 2021

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INTRODUCTION

Young permanent molars' susceptibility to caries is related to their stage of eruption (limited mechanical oral function) and the anatomy of the groove-fossa system that favors the biofilm accumulation.[1] This is probably the reason why preventive methods such as water fluoridation or fluoride toothpastes have a greater effect in reducing the prevalence of caries on smooth surfaces when compared to occlusal ones.[2]

Therefore, occlusal caries control programs should be implemented from the very beginning of tooth eruption.[1] One treatment that has been proved effective in arresting or inhibiting the carious lesions on young permanent molars is the use of pit and fissure sealant.[3-5] For this purpose, different sealant materials can be used: resin-based sealants, glass ionomer sealants (GI), polyacid-modified resin sealants and resin-modified glass ionomer sealants.[2]

Systematic reviews have compared the efficacy of the different materials in preventing dental decay in permanent molars. Clinical evidence suggests similar caries preventive effectiveness of high viscosity glass ionomer cements and resin-based sealants[6,7] as well as no superiority of resin-modified GIC and resin-based sealants[8] or between resin-modified GIC and conventional GIC.[9] Recently, one systematic review stated that the relative effectiveness of glass ionomer compared to resin sealants remains inconclusive.[10] Therefore, there is still room for further research, especially when new sealant materials are considered.

The resin-based sealants rely only on the mechanical retention on the tooth surface to prevent or arrest caries progression;[6] they act as a physical barrier that blocks the biofilm/enamel contact and they are highly moisture-sensitive. GIC sealants show hydrophilic characteristics and lower retention rates,[6,11] particularly for conventional GIC,[12] but there is an "anti-caries" effect related to the material that remains deep in the fissures and the release of fluoride inherent in GICs.[6, 13]

Even so, none of the cited materials fulfill all the requirements for an ideal fissure sealant, which includes biocompatibility, anticariogenicity, adequate bond strength to enamel, good marginal integrity, resistance to abrasion and wear and low cost.[14]

Recently, an alternative material has been launched in the market: glass carbomer cement (GCC). It is a new type of GIC that is claimed to have enhanced bioactivity compared with conventional GIC.[13] Its powder has nanocrystals of calcium fluorapatite that acts as nuclei for the remineralization process and a much finer particle size compared to GIC.[15] The manufacturer states that the incorporation of nanosized filler particles can improve compressive strength and wear resistance.[16,17]

When this product was tested as a pit and fissure sealant controversial results have been reported[18-22] in comparison to resin-based and/or glass ionomer cement.

Therefore, the purpose of this systematic review was to answer the following question: Are glass carbomer sealants more efficient in preventing/arresting carious lesions in children's permanent molars when compared to other sealant materials?

MATERIAL AND METHODS

Protocol and registration

This study protocol was registered at the PROSPERO database (CRD42016036918). The PRISMA statement recommendations were followed for its report.[23] The research was developed in December 2020/January 2021 at the State University of Ponta Grossa, Paraná, Brazil.

Information sources and search strategy

The controlled vocabulary (MeSH terms) and free keywords in the search strategy were defined based on the PICOS question:

1. Population (P): children's permanent molars.
2. Intervention (I): glass carbomer cement used as pit and fissure sealant.
3. Comparison (C): other sealant materials (GIC or resin-based materials).
4. Primary outcome (O): preventing/arresting carious lesions; secondary outcome: retention rates of sealants after at least 6 months.
5. Study design (S): randomized clinical trials (RCT).

We combined controlled vocabulary (MeSH terms) and free keywords, using the Boolean operators OR and AND to define the search strategy for the PubMed database (Table 1). Then, we adapted the PubMed search strategy to other electronic databases such as Scopus, Web of Science, the Latin American and Caribbean Health Sciences Literature database (LILACS), the Brazilian Library in Dentistry (BBO) and the Cochrane Library (Table 1).

Hand searching of the reference lists of all primary studies was carried out to find additional relevant publications. The first page of related article links of each primary study in the PubMed database was also investigated. We did not restrict studies based on publication date or languages.

The grey literature was explored using the database System for Information on Grey Literature in Europe (SIGLE). Abstracts of the annual conference of the International Association for Dental Research (IADR) and its regional

***Table 1**: Search strategy and electronic databases.*

Pubmed		
#1 molar [MeSH Terms]) OR dentition, permanent [MeSH Terms]) OR dentition, mixed[MeSH Terms]) OR dental caries [MeSH Terms]) OR "permanent molars" [Title/Abstract]) OR "permanent molar" [Title/Abstract]) OR "mixed dentition" [Title/Abstract]) OR "occlusal surfaces" [Title/Abstract	**#2** pit and fissure sealants[MeSH Terms]) OR dental fissures [MeSH Terms]) OR "caries prevention"[Title/Abstract]) OR Sealant* [Title/Abstract]) OR "pits and fissures" [Title/Abstract]) OR "pit and fissure" [Title/Abstract]) OR sealing [Title/Abstract]) OR "sealant retention" [Title/Abstract]) OR "preventing caries" [Title/Abstract]) OR "dental sealants" [Title/Abstract]) OR "fissure sealant"[Title/Abstract]) OR "sealant pleacement"[Title/Abstract]) OR "placed sealants" [Title/Abstract]) OR "sealant leakage" [Title/Abstract])	**#3** glass carbomer cement [Supplementary concept]) OR glass ionomer cements [MeSH Terms]) OR "glass carbomer" [Title/Abstract]) OR ionomer [Title/Abstract]) OR "resin sealants"[Title/Abstract])
#1 and #2 and #3		
Cochrane Library		
#1 MeSH descriptor: [Molar] explode all trees **#2** MeSH descriptor: [Dentition, permanent] explode all trees **#3** MeSH descriptor: [Dentition, Mixed] explode all trees **#4** MeSH descriptor: [Dental Caries] explode all trees **#5** permanent next molar*:ti,ab,kw or mixed next dentition:ti,ab,kw or occlusal next surfaces:ti,ab,kw (Word variations have been searched) **#6** #1 OR #2 OR #3 OR #4 or #5	**#7** MeSH descriptor: [Pit and Fissure Sealants] explode all trees **#8** MeSH descriptor: [Dental Fissures] explode all trees **#9** caries next prevention: ti,ab,kw or Sealant*: ti,ab,kw or "pit and fissure": ti,ab,kw or "pits and fissures": ti,ab,kw or sealing: ti,ab,kw (Word variations have been searched) **#10** sealant near retention: ti,ab,kw or preventing next caries: ti,ab,kw or dental next sealants: ti,ab,kw or fissure next sealant or sealant next pleacement:ti,ab,kw (Word variations have been searched) **#11** placed near sealants:ti,ab,kw *or* sealant near leakage:ti,ab,kw(Word variations have been searched) **#12** #7 or #8 or #9 or #10 or #11	#**13** MeSH descriptor: [Glass Ionomer Cements] explode all trees **#14** "glass carbomer cement":ti,ab,kw or glass next carbomer:ti,ab,kw or ionomer:ti,ab,kw or resin near sealants:ti,ab,kw (Word variations have been searched) **#15** #12 or #13
#6 and #12 and #15		

***Table 1**: Search strategy and electronic databases.*

Web of Science		
#1 TOPIC: (molar) *OR* TOPIC: (“dentition permanent”) *OR* TOPIC: (“dentition mixed”) OR TOPIC: (“dental caries”) *OR* TOPIC: (“permanent molar$”) *OR* TOPIC: (“mixed dentition”) *OR* TOPIC: (“occlusal surfaces”)	**#2** TOPIC: (“pit and fissures sealants”) *OR* TOPIC: (“dental fissures”) *OR* TOPIC: (“caries prevention”) *OR* TOPIC: (sealant$) *OR* TOPIC: (“pit* and fissure*”) *OR* TOPIC: (sealing) *OR* TOPIC: (“sealant retention”) *OR* TOPIC:(“preventing caries”) *OR* TOPIC:(“dental sealants”) *OR* TOPIC:(“fissure sealant”) *OR* TOPIC:(“sealant pleacement”) *OR* TOPIC: (“placed sealants”) *OR* TOPIC:(“sealant leakage”))	**#3** TOPIC: (“glass carbomer cement”) *OR* TOPIC: (“glass ionomer cements”) *OR* TOPIC: (“glass carbomer”) *OR* TOPIC: (ionomer) *OR* TOPIC:(“resin sealants”)
#1 and #2 and #3		
Scopus		
#1 (TITLE-ABS-KEY (molar) OR TITLE-ABS-KEY (“dentition permanent”) OR TITLE-ABS-KEY (“dentition mixed”) OR TITLE-ABS-KEY (“dental caries”) OR TITLE-ABS-KEY (“permanent molar*”) OR TITLE-ABS-KEY (“mixed dentition”) OR TITLE-ABS-KEY (“occlusal surfaces”)	**#2** (TITLE-ABS-KEY (“pit and fissures sealants”) OR TITLE-ABS-KEY (“dental fissures”) OR TITLE-ABS-KEY (“caries prevention”) OR TITLE-ABS-KEY (sealant*) OR TITLE-ABS-KEY (“pit and fissure”) OR TITLE-ABS-KEY (sealing) OR TITLE-ABS-KEY (“sealant retention”) OR TITLE-ABS-KEY (“preventing caries”) OR TITLE-ABS-KEY (“dental sealants”) OR TITLE-ABS-KEY (“fissure sealant”) OR TITLE-ABS-KEY (“sealant placement”) OR TITLE-ABS-KEY (“placed sealants”) OR TITLE-ABS-KEY (“sealant leakage”))	**#3** TITLE-ABS-KEY (“glass carbomer cement”) OR TITLE-ABS-KEY (“glass ionomer cements”) OR TITLE-ABS-KEY (“glass carbomer”) OR TITLE-ABS-KEY (ionomer) OR TITLE-ABS-KEY (“resin sealants”)) AND (LIMIT-TO (SUBJAREA , “DENT”))
#1 and #2 and #3		

***Table 1**: Search strategy and electronic databases.*

Lilacs/ BBO		
#1 (MH:molar OR MH:"dentition permanent" OR MH:"dentition mixed" OR MH:"dental caries" OR "permanent molars" OR "molares permanentes" OR "permanent molar" OR "molar permanentes" OR "mixed dentition" OR "dentición mixta" OR "dentição mista" OR "occlusal surfaces" OR "superficies oclusales" OR "superfícies oclusais")	**#2** (MH:"pit and fisure sealants" OR MH:"dental fissures" OR "caries prevention" OR "prevención de caries" OR "prevenção de cáries" OR sealant OR sellador OR selante OR sealants OR selladores OR selantes OR "pits and fissures" OR "fosas y fisuras" OR "sulcos e fissuras" OR "pit and fissure" OR "fosa y fisura" OR "sulco e fissura" OR sealing OR "caza de focas" OR vedação OR "sealant retention" OR "retención del sellador" OR "retenção de selante" OR "preventing caries" OR "prevención de caries" OR "prevenção da cárie" OR "dental sealants" OR "selladores dentales" OR "selantes dentários" OR "fissure sealant" OR "sellador de fisuras" OR "selante de fissura" OR "sealant pleacement" OR "colocación del sellador" OR "colocação de selante" OR "placed sealants" OR "selladores colocados" OR "selantes colocados" OR "sealant leakage" OR "filtración de sellador" OR "perda de selante")	**#3** (MH:"glass ionomer cements" OR"cimento ionômero de vidro" OR "glass carbomer cement" OR "cemento de vidrio carbómero" OR " cimento carbomero de vidro" OR "glass carbomer" OR "carbómero cristal" OR "carbómero de vidro" OR ionomer OR ionômero OR "resin sealants" OR "selladores de resina" OR "selantes de resina")
#1 and #2 and #3		

***Table 2**: Summary of the studies included in this systematic revie.*

Study ID	Follow-up (months)	Study design [study setting]	Subjects' mean age (mean± SD) [range]	Number subjects/ teeth	Type of teeth	Criteria for teeth to be eligible	Isolation method	Materials	Sealant Application Protocol	Outcomes evaluated (Evaluation criteria)
Elkwatehy, Bukhari, (2019)[32]	6, 12, 18, 24 months	Split mouth design [dental clinic; university]	n.r.n.r. [6-8]	44 children/ 176 teeth	First permanent molars	Fully erupted first permanent molar, ICDAS 0, 1 or 2	Cotton roll isolation	IC: ICON™ (DMG Dental Materials, Hamburg, Germany) CR: Seal It (SPIDENT CO., LTD. Kojan-dong, Namdong-ku, Incheon, Korea.) GC: GCP glass seal (GCP Dental | First ScientificDental GmbH, Elmshom, Germany) IC + CR: ICON (DMG Dental Materials, Hamburg, Germany) + Seal It (SPIDENT CO., LTD. Kojan-dong, Namdong-ku, Incheon, Korea.)	IIC: application of ICONEtch (15% hydrochloric acid) for 2 min, followed by rinsing with water for 30 s and drying with oilfree and waterfree air; the etched surface was desiccatedusing the ICON dry (99% ethanol) for 30 sfollowed by drying with oilfree and waterfree air.ICONInfiltrant syringe was placed on the targeted surfaceand the resininfiltrant dispensed. After 3 min, the excesswas wiped off and the surface was lightcured for 40 s. Finally, the infiltrant was reapplied for 1 min and light curedfor 40 s.CR: acid etching with 37% phosphoric acidgel for 30 s, rinse, dry, sealant placement over the pits and fissures, light cure for 30 s. GC: GCP sealant capsule was mixed for 7 s in a amalgamator and applied on the teeth, followed by GCP gloss application on the surface of the material with a cotton pellet and light cured for 60 s (GCP Carboled CL) IC + CR: the teeth were treated with the resin infiltrant followed by the application of SealIt. The clinical steps were described above	Sealant retentio n(score A = sealant is present in all the fissure system; score B = sealant is present in >50%; of the fissure system; score C = sealant is present in <50% of the fissure system; score D = absent sealant Development of new carious lesions (ICDAS)

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Gorseta et al., (2014)[16]	6 and 12	Split-mouth design [n.r]	8.0±2.3 [n.r]	24 children 48 teeth	First and second permanent molars	Fully erupted permanent molars with their contra-lateral tooth present-Caries-free molars-No evidence of hypoplasia-No previous sealant application	Rubber dam	CR: HeliosealF (Ivoclar Vivadent, Schaan, Liechtenstein) GC: Glass Carbomer (GCP Dental | First Scientific Dental GmbH, Elmshom, Germany)	CR: prophylaxis with pumice, enamel acid etch (30 s) (37.5% phosphoric acid Kerr Etchand[c], rinse and dry (20 s), sealant application, light polimerization (20s)GC: prophylaxis with pumice, enamel conditioning (20s) (Tooth cleaner; EDTA solution, Glass Carbomer Products[b]) rinse and dry (20 s), sealant application, light application (60s) (polymerization unit Bluephase[d] 16i - 1600 mW/cm2)	Sealant retention (Kilpatrick et al, 1996[25])* New carious lesions (score 1-absent; score 2-present.)

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Chen et al., (2012) a[19 ¥]	6, 12 and 24 months	Parallel design Multiple sealants per patient (mean 3.3 teeth) [at school]	8 years old (n.r) [7 – 9.1]	407 children 1352 teeth	First permanent molars	Fully erupted first permanent molars- No dentine carious lesions in pits and fissures - Deep and/or intermediate pits or fissures - dmft (decayed, missing and filled teeth) ≥2	Cotton wool rolls	HVGI:Ketac Molar Easymix (3M Oral Care, St Paul, MN, USA) HVGI + light: Ketac Molar Easymix (3M Oral Care, St Paul, MN, USA) GC: Glass Carbomer (GCP Dental| First Scientific Dental GmbH, Elmshom, Germany) CR: Clinpro (3M Oral Care, St Paul, MN, USA)	HVGI: tooth cleaning with wet cotton pellets, dried with dry cotton wool pellets, conditioned with glass-ionomer liquid (10s), washed and dried with cotton pellets, sealant application, finger printing technique (5-10s), petroleum jelly cover. HVGI + light: HVGI application protocol plus the application of LED curing light (60s – 750mW/cm^2) before petroleum jelly cover GC: tooth cleaning with wet cotton pellets followed by a cotton pellet dipped in Glass Carbomer Tooth Cleaner[b] (20s) , washed and dried with cotton pellets, sealant application, application of Glass Garbomer Surface Gloss[b] finger printing technique (5-10s), application of LED curing light (60s – 750mW/cm^2) CR: tooth cleaning woth rotating brush Prophy Angles[f] and suction device, rinse and dry, enamel acid etch (20s) (Scotchbond™ etchant[f]), rinse and dry, sealant application, application of LED curing light (20s – 750mW/cm^2)	Development of carious lesions

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Study ID	Follow-up (months)	Study design [study setting]	Subjects' mean age (mean± SD) [range]	Number subjects/ teeth	Type of teeth	Criteria for teeth to be eligible	Isolation method	Materials	Sealant Application Protocol	Outcomes evaluated (Evaluation criteria)
Chen et al., 2012 b[20 ¥]	6, 12, 24 and 48	Parallel design Multiple sealants per patient (mean 3.3 teeth) [at school]	8 years old (n.r) [7.0 – 9.1]	407 children 1352 teeth	First permanent molars	Fully erupted first permanent molars- No dentine carious lesions in pits and fissures - Deep and/or intermediate pits or fissures - dmft (decayed, missing and filled teeth) ≥2	Cotton wool rolls	HVGI:Ketac Molar Easymix (3M Oral Care, St Paul, MN, USA) HVGI + light: Ketac Molar Easymix (3M Oral Care, St Paul, MN, USA) GC: Glass Carbomer (GCP Dental | First ScientificDental GmbH, Elmshom, Germany) CR: Clinpro (3M Oral Care, St Paul, MN, USA)	HVGI: tooth cleaning with wet cotton pellets, dried with dry cotton wool pellets, conditioned with glass-ionomer liquid (10s), washed and dried with cotton pellets, sealant application, finger printing technique (5-10s), petroleum jelly cover. HVGI + light: HVGI application protocol plus the application of LED curing light (60s – 750mW/cm^2) before petroleum jelly cover GC: tooth cleaning with wet cotton pellets followed by a cotton pellet dipped in Glass Carbomer Tooth Cleaner[b] (20s) , washed and dried with cotton pellets, sealant application, application of Glass Garbomer Surface Gloss[b] finger printing technique (5-10s), application of LED curing light (60s – 750mW/cm^2) CR: tooth cleaning woth rotating brush Prophy Angles[f] and suction device, rinse and dry, enamel acid etch (20s) (Scotchbond™ etchant[f]), rinse and dry, sealant application, application of LED curing light (20s – 750mW/cm^2)	Sealant retention

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Study ID	Follow-up (months)	Study design [study setting]	Subjects' mean age (mean± SD) [range]	Number subjects/ teeth	Type of teeth	Criteria for teeth to be eligible	Isolation method	Materials	Sealant Application Protocol	Outcomes evaluated (Evaluation criteria)
Zhang et al, (2014)[21 ¥]	6, 12, 24 and 48 months	Parallel design Multiple sealants per patient (mean 3.3 teeth) [at school]	8 years old (n.r) [7.0 – 9.1]	407 children 1352 teeth	First permanent molars	Fully erupted first permanent molars - No dentine carious lesions in pits and fissures - Deep and/or intermediate pits or fissures -dmft (decayed, missing and filled teeth) ≥2	Cotton wool rolls	HVGI:Ketac Molar Easymix (3M Oral Care, St Paul, MN, USA) HVGI + light: Ketac Molar Easymix (3M Oral Care, St Paul, MN, USA) GC: Glass Carbomer(GCP Dental | First ScientificDental GmbH, Elmshom, Germany) CR: Clinpro (3M Oral Care, St Paul, MN, USA)	HVGI: tooth cleaning with wet cotton pellets, dried with dry cotton wool pellets, conditioned with glass-ionomer liquid (10s), washed and dried with cotton pellets, sealant application, finger printing technique (5-10s), petroleum jelly cover. HVGI + light: HVGI application protocol plus the application of LED curing light (60s – 750mW/cm^2) before petroleum jelly cover GC: tooth cleaning with wet cotton pellets followed by a cotton pellet dipped in Glass Carbomer Tooth Cleaner[b] (20s) , washed and dried with cotton pellets, sealant application, application of Glass Garbomer Surface Gloss[b] finger printing technique (5-10s), application of LED curing light (60s – 750mW/cm^2) CR: tooth cleaning woth rotating brush Prophy Angles[f] and suction device, rinse and dry, enamel acid etch (20s) (Scotchbond™ etchant[f]), rinse and dry, sealant application, application of LED curing light (20s – 750mW/cm^2)	Sealant retention (clinical evaluation and occlusal replica – SEM) Development of carious lesions (ART caries assessment criteria)**

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Study ID	Follow-up (months)	Study design [study setting]	Subjects' mean age (mean± SD) [range]	Number subjects/ teeth	Type of teeth	Criteria for teeth to be eligible	Isolation method	Materials	Sealant Application Protocol	Outcomes evaluated (Evaluation criteria)
H u et al., (2014)[31 ¥]	6, 12 and 24 months	Parallel design Multiple sealants per patient (mean 3.3 teeth) [at school]	8 years old (n.r) [7.0 – 9.1]	370 children 1095 teeth	First permanent molars	Fully erupted first permanent molars - No dentine carious lesions in pits and fissures - Deep and/or intermediate pits or fissures -dmft (decayed, missing and filled teeth) ≥2	Cotton wool rolls	HVGI:Ketac Molar Easymix (3M Oral Care, St Paul, MN, USA) HVGI + light: Ketac Molar Easymix (3M Oral Care, St Paul, MN, USA) GC: Glass Carbomer(GCP Dental | First ScientificDental GmbH, Elmshom, Germany) CR: Clinpro (3M Oral Care, St Paul, MN, USA)	HVGI: tooth cleaning with wet cotton pellets, dried with dry cotton wool pellets, conditioned with glass-ionomer liquid (10s), washed and dried with cotton pellets, sealant application, finger printing technique (5-10s), petroleum jelly cover. HVGI + light: HVGI application protocol plus the application of LED curing light (60s – 750mW/cm^2) before petroleum jelly cover GC: tooth cleaning with wet cotton pellets followed by a cotton pellet dipped in Glass Carbomer Tooth Cleaner[b] (20s) , washed and dried with cotton pellets, sealant application, application of Glass Garbomer Surface Gloss[b] finger printing technique (5-10s), application of LED curing light (60s – 750mW/cm^2) CR: tooth cleaning woth rotating brush Prophy Angles[f] and suction device, rinse and dry, enamel acid etch (20s) (Scotchbond™ etchant[f]), rinse and dry, sealant application, application of LED curing light (20s – 750mW/cm^2)	Sealant retention (clinical evaluation and occlusal replica – SEM)

***Table 2**: Summary of the studies included in this systematic revie.*

Study ID	Follow-up (months)	Study design [study setting]	Subjects' mean age (mean± SD) [range]	Number subjects/ teeth	Type of teeth	Criteria for teeth to be eligible	Isolation method	Materials	Sealant Application Protocol	Outcomes evaluated (Evaluation criteria)
H u et al., (2017)[22 ¥]	24 and 36 months	Parallel design Multiple sealants per patient (mean 3.3 teeth) [at school]	8 years old (n.r) [7.0 – 9.1]	157 children 332 teeth	First permanent molars	Fully erupted first permanent molars - No dentine carious lesions in pits and fissures - Deep and/or intermediate pits or fissures -dmft (decayed, missing and filled teeth) ≥2	Cotton wool rolls	HVGI:Ketac Molar Easymix (3M Oral Care, St Paul, MN, USA) HVGI + light: Ketac Molar Easymix (3M Oral Care, St Paul, MN, USA) GC: Glass Carbomer(GCP Dental | First ScientificDental GmbH, Elmshom, Germany) CR: Clinpro (3M Oral Care, St Paul, MN, USA)	HVGI: tooth cleaning with wet cotton pellets, dried with dry cotton wool pellets, conditioned with glass-ionomer liquid (10s), washed and dried with cotton pellets, sealant application, finger printing technique (5-10s), petroleum jelly cover. HVGI + light: HVGI application protocol plus the application of LED curing light (60s – 750mW/cm^2) before petroleum jelly cover GC: tooth cleaning with wet cotton pellets followed by a cotton pellet dipped in Glass Carbomer Tooth Cleaner[b] (20s) , washed and dried with cotton pellets, sealant application, application of Glass Garbomer Surface Gloss[b] finger printing technique (5-10s), application of LED curing light (60s – 750mW/cm^2) CR: tooth cleaning woth rotating brush Prophy Angles[f] and suction device, rinse and dry, enamel acid etch (20s) (Scotchbond™ etchant[f]), rinse and dry, sealant application, application of LED curing light (20s – 750mW/cm^2)	Sealant retention (clinical evaluation and occlusal replica – SEM)

*Note: identification; SD – standard deviation; n.r. – not reported; CR – Resin-based sealant; GC – Glass Carbomer; HVGI – high viscosity glass ionomer; IC – Icon resin infiltrant. *Criteria of Kilpatrick[25]: sealant retention: type 1 to 4 (1-intact sealant ; 2- 1/3 sealant missing; 3- 2/3 sealant missing; 4- whole sealant missing), new carious lesions (1-absent; 2-present). Score sealant retention criteria: 1 to 9 (1 –Pits and fissures completely covered with material; 2-Pits and fissures partly visible. Sharp fracture edge, creating plaque retention site; 3- Pits and fissures partly visible. Crumbled fracture edge, not creating plaque retention site; 4- Pits and fissures totally visible; If score 4 has been given then pits and fissures are re-observed using compressed air; 5- Pits and fissures totally covered with remnants; 6- Pits and fissures partly covered with remnants; 7- Other treatment performed; 9- Unable to diagnosis). **ART caries assesment criteria: 0 to 9 (0 – Sound surface; 1 – Early enamel lesion. White/opaque or brownish/dark lesion in enamel only, including loss of tooth surface; considered being active or inactive; 2- Carious lesion involving the dentine slightly; lesion cannot be penetrated with CPI probe; 3 – Dentinal lesion; lesion can be penetrated with CPI probe; 4- Dentinal lesion: pulp possibly or definitely exposed; 5 – Restoration; 6 – Sealant; 7 – Missing due to caries; 8 – Unerupted permanent tooth; 9 – Unable to make diagnosis. ¥ All the papers are different reports of only one clinical trial, approved by the Research Ethics Committee of Wuhan University (Reference No. 00704) and registered at the Dutch Trial Registration Centre (Reference No. 1411).*

divisions (1990–2016) were searched. Dissertations and theses were explored using the ProQuest Dissertations and Theses Full-Text databases and the Periodicos Capes Theses database.

Unpublished and ongoing trials were located using clinical trial registries: Current Controlled Trials (www.controlled-trials.com), International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/), the ClinicalTrials.gov (www.clinicaltrials.gov), Rebec (www.rebec.gov.br) and EU Clinical Trials Register (https://www.clinicaltrialsregister.eu).

Eligibility criteria

The included studies were RCTs with parallel or split-mouth designs that compared glass carbomer versus GIC and resin-based pit and fissure sealants in permanent molars in children. There were no restrictions regarding publication language or publication date.

RCTs were excluded if glass carbomer was not used as a sealant in permanent molars of children or if there was not a minimum follow-up period of 6 months. Case reports, in vitro studies, non-randomized trials were also excluded.

The primary outcome evaluated was the prevention of carious lesions in permanent molars; sealant retention was studied as a secondary outcome. Full-text versions of the papers that met the inclusion criteria were retrieved for further assessment and data extraction.

Study selection and data collection process

All the retrieved papers were sent to a managing software (EndNote X9, Clarivate, Philadelphia, PA). Duplicated articles were removed from the selection and considered once. Title and abstract of the retrieved studies were analyzed to check out if they met the eligibility criteria; if insufficient information prevented a decision, full-texts were used. This was done by one research (C.M.C.F.L.).

The remaining articles were classified by two reviewers jointly (C.M.C.F.L and L/M/W.) after full-text reading. An ID for each eligible study was created, combining the first author's name and year of publication. Relevant information about the study design, participants, interventions and outcomes was extracted using customized extraction forms. All the data from different sealing materials that were compared to glass carbomer sealant were grouped and annotated under the denomination "other sealants".

When there were reports with different follow-ups from the same study, data from the reports were extracted directly into a single data collection form to avoid overlapping data. This form was pilot tested to certify that the retrieved data was consistent with the research question.

Risk of bias in individual studies

The Cochrane Collaboration tool for assessing the risk of bias in RCT was used for the quality assessments of the trials.[23] This procedure was accomplished by two independent reviewers.

There are six domains in the assessment criteria: adequate sequence generation, allocation concealment, blinding of the outcome assessors, incomplete outcome data, selective outcome reporting, and other possible sources of bias. For each aspect of the quality assessment, the risk of bias was scored following the recommendations described in the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0 (http://handbook.cochrane.org). The judgment for each domain consisted of recording "yes" (low risk of bias), "no" (high risk of bias) or "unclear" (either lack of information or uncertainty over the potential for bias).

If one or more key domains were classified as "unclear" risk of bias, the study was considered at "unclear" and if at least one domain was judged as "high" risk of bias, the study was judged as "high" risk of bias. If there was any disagreement between the reviewers in judging the key domains, it was solved through discussion or by consulting a third reviewer (A.C.R.C.).

Summary measures and synthesis of the results

Data from eligible studies were dichotomous (prevalence of caries-free pits and fissures and retention rates). Studies from which data could be extracted were included in the meta-analyses. The outcomes were summarized by calculating the risk ratio/risk difference for dichotomous data. For both summary measures, the 95% confidence interval (CI) was calculated.

Random-effects models were employed. Heterogeneity was assessed using the Cochran Q test and I^2 statistics. All analyses were conducted using CMA software (version 3, Biostat Englewood, USA). No subgroup analysis was performed.

Assessment of the quality of evidence using GRADE

The quality of the evidence for each outcome across studies (body of evidence) was assessed using the Grading of Recommendations: Assessment, Development and Evaluation (GRADE) (http://www.gradeworkinggroup.org/). This determines the overall strength of evidence for each meta-analysis and classifies it into 4 levels: very low, low, moderate, high. The "high quality" suggests that we are very confident that the true effect lies close to the estimate of the effect. On the other extreme "very low quality" suggests that

we have very little confidence in the effect estimate and the estimate reported can be substantially different from what it was measured.

GRADE analyses the limitations in 5 criteria (risk of bias, imprecision, inconsistency, indirectness of evidence and publication bias) to rate down the quality of the evidence in 1 or 2 levels. Each domain was assessed as "no limitation" (no downgrade), "serious limitations" (1 level downgraded), and "very serious limitations" (2 levels downgraded). The GRADEpro Guideline Development Tool (www.gradepro.org) was used to create a summary of findings table.

Results

Study selection

After the database screening and removal of duplicates, 1053 papers were identified (Figure 1). After analysis of titles, 54 papers remained. Forty papers were excluded after the reading of abstracts, resulting in 14 full-text papers for assessment of eligibility. From these, six papers were excluded due to different reasons: in vitro studies,[24,25] non-randomized trial,[26] cost-effectivity study[27,28] prevention of carious lesions in permanent molars with micro-cavities in dentin.[29] One project of clinical trials, registered at the Dutch Trial Registration Centre (# 1441), resulted in 6 different papers[19-22,30,31] that showed data from distinct follow-up periods and outcomes. They were combined to describe the study characteristics, the risk of bias and the data to be included in the meta-analysis to avoid data overlap. Besides those papers, only two other clinical trials were identified.[18,32]

Characteristics of the included papers

The characteristics of the studies included are listed in Table 2. Two studies[18,32] used the split-mouth design; the treatments were accomplished at a university dental clinic in one of them.[32] The other six papers reported parallel design.[19-22,30,31] and the clinical procedures were carried out at primary schools in China. The mean age of the participants included in the RCTs was 8 years old.

All the included papers had samples composed of fully erupted permanent molars without dentin carious lesions.[19-22,30,31] The follow-up period of the clinical trials ranged from 6 to 12 months to 48 months. The sealants were performed with rubber dam and prophylaxis with pumice in one study.[18] In the other studies, isolation with cotton rolls were used.[19-22,30,31]

The materials used for pit and fissure sealing were glass carbomer (GC Products, Leiden, Netherlands),[18-22,30-32] which was compared to high viscosity GIC,[19-22,30,31] resin-based sealants[18-22, 31] and resin infiltrant.[32]

The prevalence of carious lesion-free pits and fissures was based on a yes/no criteria,[18] International Caries Detection and Assessment. System (ICDAS)[32] or with a 0-9 scale (ART caries criteria).[19-22,30,31] The evaluation criteria used for assessment of the sealant retention were not the same. In one study,[18] the authors used the Kilpatrick criteria[33] for sealant evaluation with scores ranging from 1 to 4; other papers[19-22,30,31] used clinical exam and occlusal replicas; and the other study used scores from A to D.[32]

Assessment of the risk of bias

The risk of bias of the selected studies is presented in Figure 2. One study was judged to be at unclear risk of bias,[18] the other studies were judged to be at low risk of bias.[19-22,30-32]

Meta-analysis

All meta-analyses were performed for the outcomes "prevalence of new carious lesions" and "sealant retention" in three follow-up periods: 6, 12 and 24 months.

Prevalence of new carious lesion

The meta-analyses related to the outcome "prevalence of new carious lesions" are presented in Figure 3.

No difference between glass carbomer sealants and the other sealant materials was detected for 6 (p=0.63) and 12 (p=0.81) months follow-up periods; these meta-analyses showed no heterogeneity (I^2=0%). The quality of the evidence for both periods was graded as "low", which means that the confidence in the effect estimate is limited and the true effect may be substantially different from the estimated effect. The quality was downgraded two levels due to imprecision because the optimal information size was not met and the confidence interval doesn't exclude benefit or harm (Table 3).

However, after 24 months, other sealant materials performed better than glass carbomer sealant (p=0.002) and the meta-analysis showed low heterogeneity (I^2=7%). For this outcome, the quality of the evidence was graded as "moderate", since we are moderately confident that the true effect is close to the estimate of the effect, but there is yet a possibility that it is substantially different. The quality was downgraded one level due to imprecision since the optimal information size was not met (Table 3).

Sealants retention

The meta-analyses related to the outcome "sealant retention" for 6, 12 and 24 months follow-up periods are presented in Figure 4. Regardless, the follow-up period, no differences were detected between glass carbomer sealant and other sealant materials tested (p<00001). All the analyses exhibited heterogeneity values higher than 95%. The quality of evidence for all the evaluation periods was graded as "very low". It means that there is little confidence in the estimated effect and that the true effect probably is different from the estimated one. The quality of evidence was downgraded in two levels for inconsistency and imprecision, which is related to non-explained heterogeneity and a wide confidence interval, respectively (Table 4).

Table 3: *Summary-of-findings table and quality of the evidence regarding the outcome "development of new carious lesions". Only comparisons with meta-analysis were included.*

Development of new carious lesions in permanent molars in children: Glass carbomer X other sealing materials

Outcomes	Nº of participants (studies)Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with other sealants	Risk difference with glass carbomer sealant
New carious lesions - 6 months	1515(3 RCTs)	⊕⊕◯◯ LOW [a]	**Rate ratio 0.00** (0.01 to 0.00)	0 per 1000	**0 fewer per 1000** (0 fewer to 0 fewer)
New carious lesions - 12 months	1515(3 RCTs)	⊕⊕◯◯ LOW [a]	**RR 1.15** (0.36 to 3.72)	8 per 1000	**1 more per 1000** (5 fewer to 22 more)
New carious lesions - 24 months	1804(2 RCTs)	⊕⊕⊕◯ MODERATE [b]	**RR 1.93** (1.27 to 2.93)	37 per 1000	**35 more per 1000** (10 more to 72 more)

*Note: *The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval; RR: Risk ratio. GRADE Working Group grades of evidenceHigh certainty: We are very confident that the true effect lies close to that of the estimate of the effectModerate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially differentLow certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effectVery low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect. Explanations: a. The optimal information size criterion was not met, there were few events and the CI included appreciable benefit and harm; b. The optimal information size criterion was not met.*

Table 4: *Summary-of-findings table and quality of the evidence regarding the outcome "sealant retention". Only comparisons with meta-analysis were included.*

Sealant retention in permanent molars in children: Glass carbomer X other sealing materials

Outcomes	Nº of participants (studies)Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with other sealants	Risk difference with glass carbomer sealant
Sealant retention -6 months	1515(3 RCTs)	⊕◯◯◯ VERY LOW [a,b]	**RR 0.12** (0.13 to 0.38)	79 per 1000	**70 fewer per 1000**(69 fewer to 49 fewer)
Sealant retention - 12 months	1515(3 RCTs)	⊕◯◯◯ VERY LOW [a,c]	**RR 2.12** (0.49 to 9.16)	170 per 1000	**191 more per 1000**(87 fewer to 1391 more)
Sealant retention - 24 months	1436(2 RCTs)	⊕◯◯◯ VERY LOW [a,c]	**RR 2.02** (0.51 to 8.07)	289 per 1000	**295 more per 1000**(142 fewer to 2046 more)

*Note:*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval; RR: Risk ratio. GRADE Working Group grades of evidenceHigh certainty: We are very confident that the true effect lies close to that of the estimate of the effectModerate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially differentLow certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effectVery low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect. Explanations: a. Inconsistency in the data due to high and non-explained heterogeneity; b. Imprecision due to a high confidence interval that does not exclude great benefit or great harm; optimal information size was not reached; c. Imprecision due to a high confidence interval that does not exclude great benefit or great harm.*

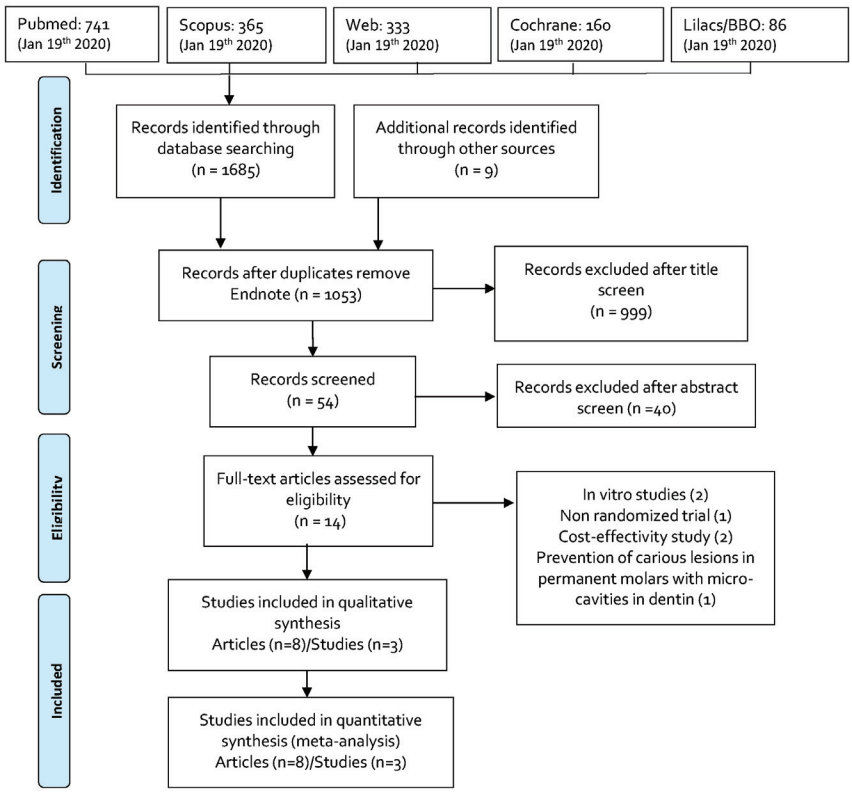

Figure 1: *Flow diagram of included studies.*

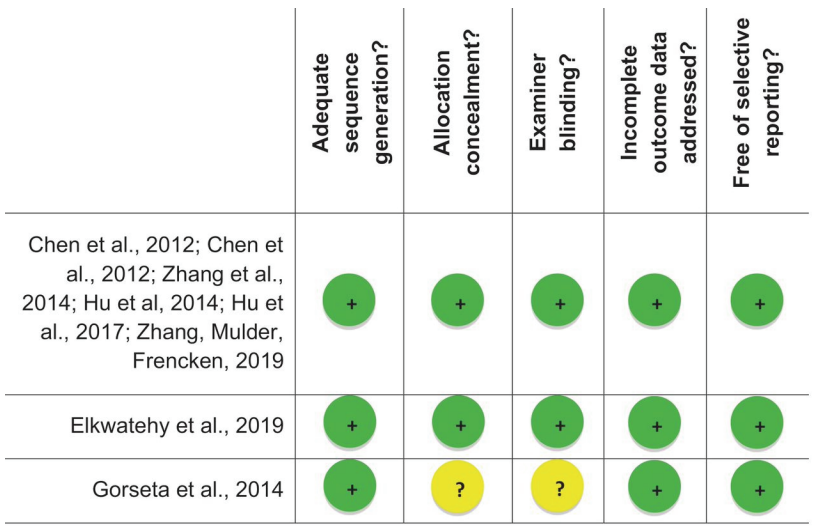

Figure 2: *Summary of the risk of bias assessment according to the Cochrane Collaboration tool.*

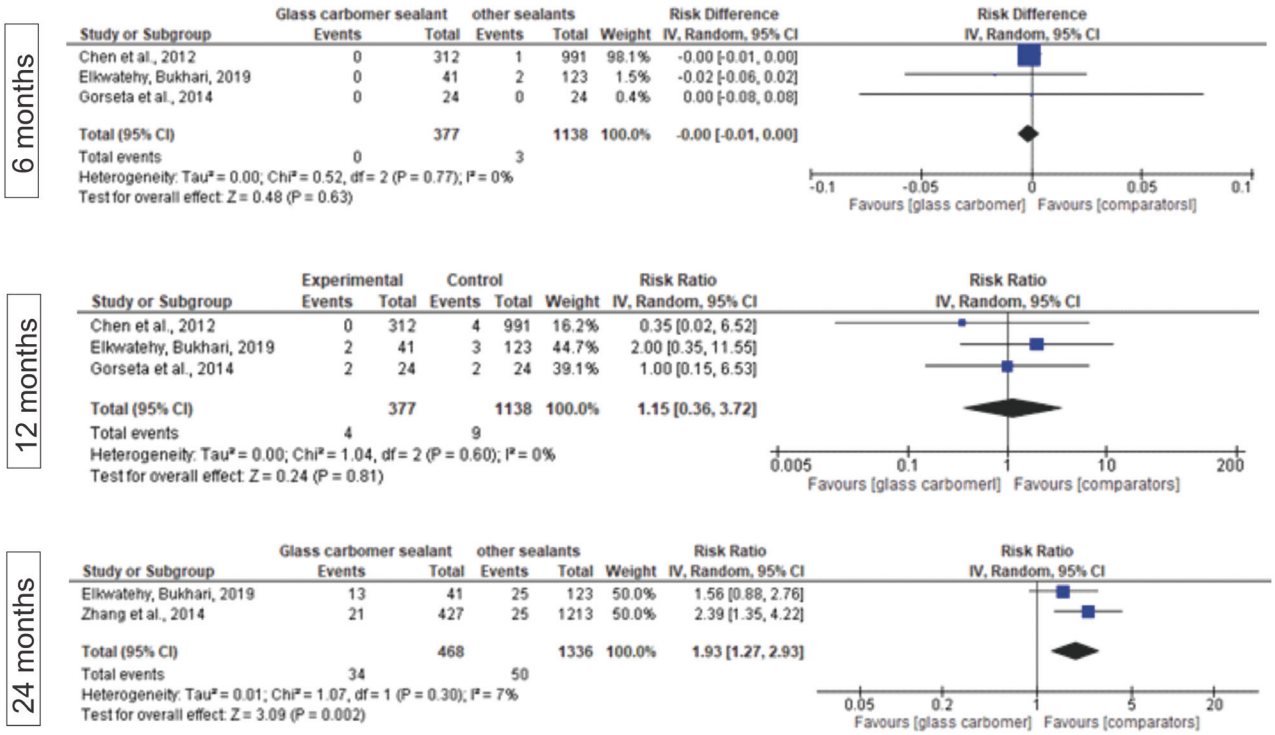

Figure 3: *Forest plots of development of new carious lesions after 6, 12 and 24 months of follow-up.*

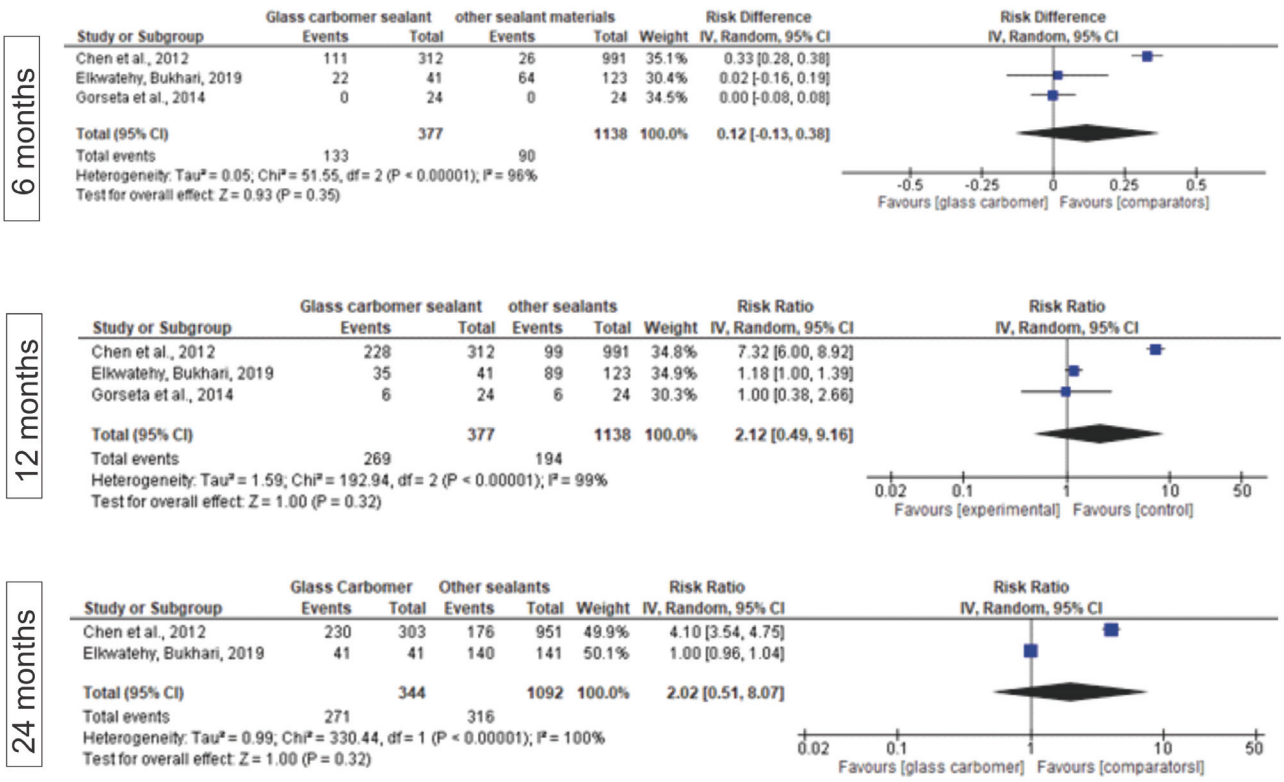

Figure 4*: Forest plots of sealant retention after 6, 12 and 24 months of follow-up.*

DISCUSSION

This systematic review and meta-analysis showed that glass carbomer sealants have a similar performance to other sealant materials when the prevalence of new caries lesions and sealant retention are considered. However, this finding must be taken carefully since the quality of the evidence is low or very low and these results may be modified by new clinical trials. An exception was found for the development of new carious lesions, which seems to achieve better results when other sealing materials are used after 24 months.

Glass carbomer is a restorative material that shares some characteristics with glass ionomer cements, such as the setting process based on an acid-base reaction[15] and the adhesion to mineralized dental substrate based on ion exchange between the material and the tooth.[34] But the interest in studying glass carbomer cement relies on some differences in the cement composition such as the presence of nanocrystals of calcium fluorapatite and much finer particle size. As a result, this material should show enhanced mechanical properties,[15] with bioactivity and probably, good survival rates. Therefore, when using this restorative material as a pit and fissure sealant, it would be expected better than or at least similar clinical behavior as GIC sealants would be expected, even without complete sealant retention.

This assumption was confirmed regarding the development of new carious lesions until 12 months of follow-up, and glass carbomer sealants showed similar performance as the other sealing materials. However, for the 24 months evaluation, HVGIC, HIGIC activated with light and resin-based sealants performed better. This finding is important, but must be interpreted carefully, since the quality of the evidence is moderate.

This finding should be emphasized, considering that the retention of pit and fissure sealants are commonly the main outcome used in clinical trials to evaluate the efficacy of sealants in preventing caries[14] and its ability to remain intact and bonded to the enamel surface for a lifetime is the main goal. [35]

This may be true for resin-based sealants, but not for glass ionomer sealants. The logic behind the use of retention as a measure of sealant efficacy was investigated and has been contradicted by the current evidence.[36,32] A recent systematic review could not find evidence associating the loss of the GIC sealants and the development of carious lesions[37] and therefore considered the prevention of carious lesions as a surrogate endpoint for sealant retention. An update from a Cochrane systematic review also considered the prevention of occlusal carious lesions as the primary outcome.[10] After all, the final objective when a clinician indicates such procedure is to prevent the development of carious lesions in susceptible teeth. That is the reason why this systematic review considered both factors as outcomes for the meta-analysis: the prevention of carious lesions in a more contemporary approach and the sealant retention as the usual outcome.

Regarding retention rates, glass carbomer sealants showed similar clinical performance as other sealing materials, but the quality of the evidence regarding this outcome was considered low or very low. The included studies [18,19,32] exhibited several differences in treatment settings and procedures. These differences may have affected the estimate effects and could explain the high heterogeneity, which makes the estimated pool effect of retention rates not reliable. Additionally, this pooled effect estimate suffers from inaccuracy and we cannot exclude a clinically important benefit or harm when using glass carbomer sealants.

Among the differences between studies, some factors may have some influence on the performance of the sealants. Higher rate retention of GIC sealants can be obtained when the sealant is placed under the finger press technique. The cleaning method is also important. For resin-based sealants, authors showed that occlusal surfaces cleaned with pumice slurry provided significantly higher retention than brushing and no cleaning.[38]

There are also inherent differences related to the comparators used against glass carbomer sealant. Resin-based sealants protocol includes acid-etching techniques, which provide higher bond strength to the enamel;[24] these sealants also show lower viscosity[39] when compared to GIC ones, which may affect the material penetration into the fissures.[40]

Regardless of the described factors, sealants deteriorate over time and the enamel surface may be exposed to the oral environment and the cariogenic challenge again. It is the current assumption that GIC sealants fracture cohesively and remnants of the sealant are left behind in the deeper parts of the fissures.[22] Notwithstanding, it was showed that this may be true also for resin and glass carbomer sealants.[22] The analysis of colored pictures and SEM images revealed that the remnants of GIC, glass carbomer and resin-based sealants are similar after 2 and 3 years.[22] This remaining material modifies the anatomy of the fissures and facilitates the removal of dental plaque by tooth brushing from fissures that otherwise would be inaccessible [22], it also promotes some release of fluoride to the adjacent enamel.[41,42] Both processes seem to explain the lack of caries progression even after total or partial loss of the sealant.

Finally, we should not deny that the present systematic review and meta-analysis was based on only three available studies regarding the clinical performance of glass carbomer as a sealant in permanent molars. Further high-quality RCTs are needed to

improve the quality of the evidence regarding this subject. Therefore, considering the clinical performance and the costs of the glass carbomer cement, we still can not suggest the use of glass carbomer sealants over other sealing materials

CONCLUSIONS

Glass carbomer sealants have a similar performance to other sealant materials when sealant retention is considered. For the development of new carious lesions, other sealant materials performed better over time. However, new clinical trials are needed to corroborate these findings since it still lacks quality to the evidence obtained.

ACKNOWLEDGMENTS

This study was partially supported by the National Council for Scientific and Technological Development from the Brazilian Government, under grants 304105/2013-9 and 305588/2014-1 and the Coordination of Improvement of Higher Level Personnel (CAPES) from the Brazilian Ministry of Education.

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