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Success rate of proximal toothcoloured direct restorations in primary teeth at 24 months: a meta-analysis

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The aim was to determine the survival of tooth-coloured restorative materials in proximal restorations of primary teeth at 24 months of follow-up and the influence of the following variables: use of coating, use of cavity conditioner, use of rubber dam isolation, the cavity form, the dentist's experience and the methodological characteristics of the studies. We conducted a search until May 2019, obtaining 16 articles from which 30 independent studies were extracted, which were considered as units of analysis. Four outcome measures were extracted from each study: retention, marginal integrity, anatomic form, and absence of recurrent caries. Separate meta-analyses were carried for each outcome and multiple meta-regression model was applied. The outcomes with the highest mean success rates were absence of recurrent caries and anatomic form. The type of material significantly influenced success rates. The best materials were resin-based material plus total-etching adhesion and resin-modified glass ionomer cement (RMGIC), and the worst high viscosity glass ionomer cement (HVGIC). Atraumatic restorative treatment (ART) had a lower success rate than the conventional cavity form. RMGIC had the best clinical performance and HVGIC the worst. The form of the cavity, blinding and the experience of the operator were the variables that influenced success rates. Proximal primary molar restorations should be performed with RMGIC as it combines good mechanical performance of the resins together with the prevention of secondary caries of glass ionomers.

The Global Burden of Disease 2015 study¹ concluded that oral health has not improved in the last 25 years: the age-standardized prevalence rate of untreated caries in primary teeth was 7.8% (573 million children) and 126 million children worldwide had incident cases of caries in primary teeth in 2015. Dental caries, according to the WHO, remains the most frequent chronic disease in early childhood in most communities around the world, having a negative impact on the quality of life of both the child and their family, and is considered a public health problem^{2,3}.

The toxic effects on the patient, health professionals and the environment, the increasing prevalence of minimal intervention restorative approaches and the increased demand for aesthetics, have reduced the use of amalgam as the material of choice for the restoration of primary teeth 4.5. Currently, restorative treatments for primary teeth include a wide variety of tooth-coloured materials such as glass ionomer cements (GIC), resin-modified glass ionomer cement (RMGIC), high viscosity glass ionomer cement (HVGIC), compomers and composite resins (CR). In general, composites are recommended in children with a low risk of caries, compomers in children with a moderate risk and glass ionomers in children with a high risk.6.

GICs are good materials for the primary dentition⁷ due to their ability to adhere to the dental structure, low polymerization contraction, lack of postoperative sensitivity, biological compatibility and the anti-cariogenic effects of fluoride release⁸. However, their low resistance to fracture and wear does not make them suitable materials for proximal restorations, with a failure rate of 6.6–60% at 36 months⁹. RMGICs, whose composition includes resin, improve the physical and aesthetic properties of GICs, while maintaining their potential for fluoride release^{10–12}. HVGICs maintain the mechanical properties offered by resins (microhardness, resistance to

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abrasion and fracture) without containing resins, and have performed well in reconstructions of the posterior sector in primary and permanent dentition^{13,14}.

CRs have been used as a substitute for amalgams, with good short-term performance in both occlusal and proximal restorations. However, due to the problems derived from polymerization contraction (loss of retention, microfiltration and secondary caries) and because these materials are very sensitive to the technique used and require a demanding placement protocol¹⁵, this has led paediatric dentists to search for alternatives. Compomers and giomers, which present the mechanical and aesthetic properties of a composite together with the ability to release fluoride, have been used in proximal cavities of primary teeth^{16–20}.

Paediatric dentists have, therefore, a wide range of materials for the restoration of proximal cavities, or class II, in primary teeth. In choosing the material, one important factor should be considered: the longevity/survival of the restoration, since the replacement of failed restorations is a problem for patients, professionals and public health systems¹⁹. The success rate of the restoration depends on the properties of the material, the level of the risk of caries, the state of the tooth affected, the characteristics of the patient and the dentist's ability in the use of the materials and in handling the child's behaviour^{15,21}.

A 2007 meta-analysis of 21 studies concluded that, of the coloured restorations in primary molar proximal lesions followed for at least 1 year, RMGIC had the highest clinical success rates, although only one RMGIC product was assessable²². A 2009 systematic review studied all types of restorative materials used in primary dentition [silver amalgam, GICs, silver reinforced glass ionomer cements (SRGICs), RMGICs, CR, stainless steel crowns and compomers], all types of cavities (classes I to V) and different cavity preparations [decay removed using drills, and ART removing decay with manual instruments only] with a follow up of >6 months. They could only include three studies and these did not provide sufficient evidence to make any recommendations about which filling material to use²¹. A systematic review and meta-analysis, published in 2016, analysed the survival time of adhesive restorations (CR, GIC, RMGIC, SRGIC, and componer) for class I and II of primary molars, and concluded that there was weak evidence that adhesive materials with a resin component have similar survival rates for 24 months and up to 48 months and that there was no evidence that adhesive materials with a resin component in the formula had a greater survival rate than glass ionomer cement²⁴. A systematic review studied, in 2018, the survival of restorations (class I, class II, and crown) placed using different materials in primary teeth with at least one year of follow-up. They found large variations in the annual failure rates (0-29.9%) due to the differences in the techniques and material evaluated. The lowest annual failure rate was in class I restorations using a rubber dam and those using CR (1.7-12.9%) and the highest success rate was for stainless steel crowns $(96.1\%)^{21}$.

It is necessary to determine the success rate of tooth-coloured materials used in the restorations of proximal classes of temporary teeth, including those marketed in recent years, such as HVGIC and giomers. Therefore, the main objective of this meta-analysis was to determine which tooth-coloured restoration material is most suitable for proximal fillings in primary teeth. The question posed was: What will the survival of different tooth-coloured restorative materials in proximal restorations of primary teeth be at 24 months? The secondary objective was to determine factors influencing the success of the tooth-coloured restoration material at 24 months. The null hypothesis of our study was that the success rate at 24 months of proximal restorations of primary teeth does not depend on the tooth-coloured material used.

Materials and methods

The meta-analysis was carried out according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) method²⁵. Supplementary File 1 shows the PRISMA checklist. The protocol was registered in the PROSPERO international database for systematic reviews (CRD42019138646).

Inclusion and exclusion criteria. Using the components of the Participants, Interventions, Comparisons, Outcomes, and Study designs (PICOS) system²⁶, the studies to be included in this meta-analysis the studies had to meet the following criteria:

- Participants: primary teeth with proximal caries in children aged 2–14 years.
- Interventions: tooth-coloured proximal (or class II) restorations (composites, compomers, RMGIC, HVGIC and giomers) evaluated in vivo.
- Comparisons: Not applicable.
- Outcomes: Success rate at 24 months of follow-up for retention, marginal integrity, anatomic form, and absence of recurrent caries.
- Study designs: randomized controlled trials (RCTs), non-randomized controlled trials (nRCTs), and uncontrolled trials.

In addition, published and unpublished studies were accepted. We excluded reviews, clinical cases, *in vitro* studies, observational studies, studies of permanent teeth, studies evaluating the survival of materials in classes I, III, IV and V, studies dealing only with amalgam or cermet restorations or stainless steel crowns, and studies with a follow up other than 24 months.

Search strategy. We exhaustively searched the following electronic databases: PubMed, MEDLINE, SciELO, Embase, Scopus, WOS, LILACS and BBO. We also carried out a manual search to find studies not included in the electronic databases. We adapted the search strategy to the requirements of each database. The references of the studies recovered were also reviewed to identify studies that might fulfil the selection criteria. The search languages were English, Spanish and Portuguese, and the search covered 1985 to May 2019. We included the following search terms, making the appropriate adaptations to the language required by the different databases:

"survival", "durability", "primary", "deciduous", "teeth", "class II", "proximal", "occlusoproximal", "composite", "compomer", "glass ionomer", "high viscosity glass ionomer", "resin modified glass ionomer" and "giomer".

Studies were selected in a three-stage procedure. First, the title of the study was considered. Studies that appeared in the results of more than one database were only taken into account once, and all duplicate studies were eliminated. Secondly, we read the abstracts of the articles. If the summary did not provide sufficient information to make a decision about its inclusion or exclusion, we reviewed the entire study before making the final decision. Thirdly, we considered the full text to determine its inclusion or exclusion. Selection was made independently by two authors (AJOR, NPG). Subsequently, the authors discussed studies in which there were discrepancies until a consensus was reached.

Data extraction. The most relevant data were extracted from the articles and included in a database which collected the main characteristics of the intervention and the evaluation criteria of the restoration materials. The complete database is shown in Supplementary Dataset file. For the extraction of the results, within the same article, each restoration material, or the same material under different experimental conditions, was considered as an independent study.

All materials were classified into five types: resin-based materials bonded using total etching (which includes: composites, giomers, compomers, fluid composites); resin-based materials bonded with a self-etching adhesive (composites, compomers, fluid composite); open-sandwich technique (RMGIC as base plus composite); RMGIC; and HVGIC.

To compare the results of the studies, the evaluation criteria of the different systems used were unified into four categories (Supplementary File 2). These systems were: United States Public Health Service (USPHS) criteria by Ryge and Cvar in 1971^{11,27}, USPHS modified by Ryge and Snyder in 1973²⁸, USPHS modified by Ryge in 1980^{12,18,29–32}, USPHS modified by Van Dijken in 1986^{16,33–35}, USPHS modified by Ryge in 1980 and ART modified criteria³⁶, own system³⁵, FDI criteria²⁰.

The four evaluation categories used were:

- Retention. No detachment of the material and no partial or total fracture that required repair or a new restoration.
- Marginal integrity. No discoloration, filtration or defects in marginal adaptation.
- Anatomic form. No alterations in the shape and texture of the surface of the restoration.
- Absence of secondary caries.

The most relevant characteristics of the intervention studied were:

- Conditioning of the cavity, referring only to glass ionomer materials.
- Coating (only glass ionomers materials).
- Complete isolation with rubber dam.
- Cavity form, differentiating between cavities made according to ART principles (manual cavities made with spoon) and conventional cavities (cavities made by using rotary instruments and burrs).
- Operator experience, considering non-graduate student as inexperienced and graduate dentists as experienced.

The following patient characteristics were extracted: mean and SD of age (in years) and sex (% male). The following methodological characteristics were extracted: design (RCT, nRCT, or uncontrolled trial), random assignment, blinded assessment, reporting bias, and sample size. Financial sources and year of the study were also extracted. To check the reliability of the extraction of the study characteristics, two independent coders doubly coded all studies. The results were highly satisfactory overall, with kappa coefficients ranging between 0.927 and $1.0 \, (\text{mean} = 0.993)$ for categorical variables, and intra-class correlations between 0.805 and $1.0 \, (\text{mean} = 0.979)$ for continuous variables. Inconsistencies between the coders were resolved by consensus.

Statistical analysis. From each sample, the proportions of success at 24 months were extracted for the four outcome measures: retention, marginal integrity, anatomic form, and absence of recurrent caries. Separate meta-analyses were made for each outcome. To normalize the distribution of the success rates, they were transformed using the logit event rate: $Lp = Ln \left[p/(1-p) \right]$, with p being the success rate, Ln the natural logarithm, and Lp the logit event rate. In each meta-analysis, a random-effects model was assumed³⁸ and, consequently, the logit event rates were weighted by the inverse variance, defined as the sum of the within-study and between-studies variance. The latter was estimated using the DerSimonian and Laird method³⁹. The sampling variance of each logit event rate, V(Lp), was calculated as: V(Lp) = 1/(np) + 1/[n(1-p)], with n being the sample size. Subsequently, the results were back-transformed to success rates to facilitate interpretation by means of: $p = e^{Lp}/(e^{Lp} + 1)$, with e being the base of the natural logarithm⁴⁰. In each meta-analysis, the 95% confidence limits around the mean success rate were computed using the method proposed by Hartung⁴¹. The heterogeneity of the success rates was assessed by constructing a forest plot and calculating the Q statistic and the I^2 index. I^2 values of about 25%, 50%, and 75% can be considered as reflecting low, moderate, and high heterogeneity⁴². To test whether publication bias was a threat to the validity of the meta-analytic results, funnel plots were constructed applying the trim-and-fill method⁴³.

If studies were found to have heterogeneity, moderator analyses were carried out using meta-regressions and weighted ANOVAs for continuous and categorical variables, respectively, assuming a mixed-effects model 44,45 . The improved F statistic proposed by Knapp and Hartung 46 was applied to test the significance of the moderator variables. $Q_{\rm E}$ and $Q_{\rm W}$ statistics were applied to examine model misspecification for the continuous and categorical

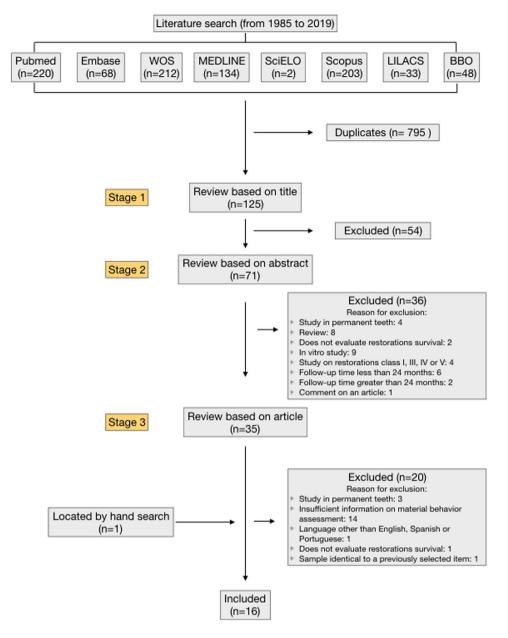


Figure 1. Flow chart for search strategy.

moderators, respectively. The proportion of variance accounted for by the moderator variables was estimated using R^2 , an index that takes into account the total and residual between-studies variance⁴⁷. Finally, to identify the study characteristics that best explained variability of the success rates, a multiple meta-regression model was applied. The moderator variables included in the model were selected taking into account both statistical and practical significance achieved in the previous analyses. All statistical analyses were carried out with the metafor package for R^{48} .

Results

Results of the systematic search. Figure 1 shows a flowchart of the selection process. The search strategy yielded 920 articles: 220 from PubMed, 68 from Embase, 212 from WOS, 134 from MEDLINE, 2 from SciELO, 203 from Scopus, 33 from LILACS and 48 from BBO. After excluding 795 duplicate articles, 125 articles remained. Seventy-one articles were accepted due to the title and, after reading the corresponding abstracts, 36 were excluded, due to:

- Study in permanent teeth: 4.
- Systematic review: 8.
- Did not evaluate restoration survival: 2.
- In vitro study: 9.

- Study of restorations class I, III, IV or V: 4.
- Follow-up time <24 months: 6.
- Follow-up time >24 months: 2.
- Comment on an article: 1.

After complete reading of the remaining 35 articles, 20 were excluded due to:

- Study in permanent teeth: 3^{49–51}.
- Insufficient information on evaluation of material performance: 14^{10,19,52-63}.
- Language other than English, Spanish, Portuguese: 1. (Summary in English, full article in Korean)⁶⁴.
- Did not evaluate restoration survival: 165.
- Identical to a previously selected item: 1. One article was found with a different title but with the same authors and an identical sample. We excluded one of the two articles 66.

One more article was located by manual search. Finally, 16 articles were selected for review^{11,12,16,18,20,27-37}.

Descriptive characteristics of the studies. The 16 articles included in the meta-analysis were published over a 20-year period. The first, carried out by Andersson-Wenckert *et al.*²⁸, was published in 1995, and the last, by Sengul and Gurbuz²⁰, in 2015. Seven were randomized controlled studies^{11,18,27,32,34,36,37}, five were controlled non-randomized trials^{12,20,29-31}, and four were uncontrolled, non-randomized trials^{16,28,33,35}. Randomization was correct in seven^{11,18,27,32,34,36,37} articles and incorrect or undefined in the remaining nine^{12,16,20,28-31,33,35}. Among the articles with correct randomization, this was done by computer in three^{18,27,32}.

In nine studies, the dentists who evaluated the restorations were unaware of the material used, as they were triple blinded 11,12,16,31,32,34,36,37 . In 14 articles there was no reporting bias $^{11,12,16,18,20,27,29,31-37}$, and 15 articles did not declare whether there were conflicts of interest or not $^{11,12,16,18,20,27-31,33-37}$. The source of funding was public in six of the articles 11,16,28,33,34,37 and private or mixed in the remaining $10^{12,18,20,27,29-32,35,36}$. Thirty independent studies were extracted from the 16 articles selected. The most important characteristics of each study are shown in Table 1.

Mean success rates and heterogeneity. Table 2 shows the mean success rates, the 95% confidence intervals, and the heterogeneity statistics (Q and I^2) for each outcome. The absence of recurrent caries and anatomic form were the outcomes with the highest mean success rates ($p_+=0.909$ and $p_+=0.901$, respectively). The mean success rates for marginal integrity and retention were 0.898 and 0.879, respectively. As retention was the main outcome, Fig. 2 shows a forest plot of the 27 retention success rates, and Supplementary File 3 shows the forest plots of the success rates for marginal integrity, anatomic form and absence of recurrent caries. The Q statistic was significant (p < 0.0001) for all four outcomes and the I^2 indices were >75% in all cases (Table 2). The wide heterogeneity of the success rates was investigated by analysing the influence of moderator variables.

Analysis of publication bias. To determine whether publication bias was a threat to the conclusions of the meta-analysis, funnel plots were constructed applying Duval and Tweedie's trim-and-fill method. Figure 3 shows the funnel plot of the retention success rates, with a slightly higher concentration of data on the right side of the mean success rate. By applying the trim-and-fill method, seven additional success rate estimates were imputed to achieve symmetry in the funnel plot. Adding the seven success rates led to a slight decrease in the mean success rate from the original 0.879 to 0.839 (95% CI: 0.764–0.893), implying a 4.8% decrease, which may be considered negligible. Therefore, publication bias did not threaten the overall success rate for retention outcome.

Similar analyses were carried out for the other three outcomes. Supplementary File 3 presents the funnel plots for marginal integrity, anatomic form, and absence of recurrent caries. For both marginal integrity and anatomic form, five new success rates were imputed to adjust the funnel plots to symmetry (see Supplementary Figs 4 and 5, respectively). The mean success rates for marginal integrity obtained with the 27 original success rates and after imputing data, were 0.898 and 0.881 (95% CI: 0.832–0.916), respectively, with a negligible decrease of 1.9% when data imputation was applied. For anatomic form, the mean success rates for the original and once imputed data were 0.901 and 0.876 (95% CI: 0.817–0.919), respectively, implying a negligible decrease of 2.9%. With respect to the absence of recurrent caries, the trim-and-fill method added eight success rates on the left side of the funnel plot to achieve symmetry (see Supplementary Fig. 6 in File 3), leading to a decrease in the mean success rate from 0.909 (with the 24 original success rates) to 0.878 (95% CI: 0.828–0.915) once data were imputed. In this case, the decrease of 3.5% can also be considered negligible. Therefore, these results enabled publication bias to be ruled out as a threat to the validity of the meta-analytic results.

Analysis of moderator variables. The analysis of moderator variables was carried out separately for the four outcomes. We only present here the results of the retention outcome, since the pattern of results was very similar for the remaining outcomes. However, the results of applying ANOVAs and simple meta-regressions for the marginal integrity, anatomic form and absence of recurrent caries are shown in Supplementary File 4. Table 3 presents the simple meta-regressions applied for each continuous moderator variable on the estimated retention success rates. Of the moderators analysed, only sample size was significantly negatively associated with the success rates (p = 0.001), accounting for 37% of variance. A marginally significant result was found for anatomic form (p = 0.052, accounting for 17% of variance; see Table 3 in Supplementary File 4).

Regarding categorical moderators, Table 4 shows the results of the weighted ANOVAs applied to the estimated retention success rates. The type of material significantly influenced the success rates (p = 0.011), explaining 36% of variance. Specifically, better results were found for resin-based material plus total-etching adhesion (p_+ =

Study	Participants (number of children, average age and interval)	Materials (n)	Cavity conditioner (*)	Coat	Cavity form	Dentist experience	Rubber dam	Retention success rate	Marginal integrity success rate	Anatomic form success rate	Absence of recurrent caries success rate
Andersson- Wenckert et al ²⁸ .	25 children. ā: 8[6-10]	ChemFil II n = 44	Durelon liquid (40% polyacrylic acid)	yes (protecting varnish)	Conventional	Experienced	No	0.86	_	0.86	0.9
Andersson- Wenckert et al. 16	79 children. ā: 8[5–12]	Dyract n=113	Dyract primer	No	Conventional	Experienced	No	0.8	0.95	0.96	0.95
Folkesson et al. 33	85 children. ā: 7.8[4–12]	Vitremer _™ n=134	Vitremer™ Primer	No	Conventional	Experienced	No	0.96	0.95	0.96	0.95
Espelid <i>et al.</i> (1999) ²⁹	43 children. ā: 7.8 ± 1.5[5–11]	Vitremer™ n=44	No	Vitremer™ Gloss	Conventional	Experienced	Not specified	0	0	_	2.27
Attin <i>et al</i> . (2000)a ³⁰	52 children [3.8 – 10.6]	TPH Spectrum + Prime- Bond _™ 2.0 n=71	_	_	Conventional	Experienced	no	0.97	0.94	1	0.97
Attin <i>et al</i> . (2000)b ³⁰	52 children [3.8 – 10.6]	Compoglass _* + Single Component Adhesive n = 70	_	_	Conventional	Experienced	no	0.94	0.93	1	1
Lo et al. (2001) a ³⁶	[6-14]	ChemFlex ₁₈ n = 13	IV liquid diluted 50% with H ₂ O	No	ART	Experienced	no	41.6	8.3	8.3	0
Lo et al. (2001) b ³⁶	[6-14]	Fuji IX GP n = 13	IV liquid diluted 50% with H ₂ O	No	ART	Experienced	no	30.8	7.7	15.4	2.6
Kavvadia <i>et al.</i> (2004) ¹⁸	75 children ā: 7 ± 1.2[6–9]	F2000 + Clicker n = 57	_	_	Conventional	Experienced	Yes	1	1	1	0.96
Ersin <i>et al.</i> (2006)a ¹²	219 children ā: 8.07 ± 1.51 [6–10]	Fuji IX GP n = 72	GC Dentin Conditioner	Fuji Varnish	ART	Experienced	No	0.75	0.75	0.75	0.72
Ersin <i>et al.</i> (2006)b ¹²	219 children ā: 8.07 ± 1.51[6- 10]	Surefil + Xeno III n=75	_	_	ART	Experienced	No	0.81	0.81	0.81	0.75
Anderson- Wenckert <i>et al.</i> (2006)a ³⁴	57 children. ā: 8[5–11]	Vitremer ₁₉₄ n = 53	Vitremer _™ Primer	No	Conventional	Experienced	no	3.77	4	8.2	3.77
Anderson- Wenckert <i>et al.</i> (2006)b ³⁴	57 children. ā: 8[5–11]	Tetric Flow _* + Excite _* n = 54	No	No	Conventional	Experienced	yes	3.70	6.1	4.1	8.0
Anderson- Wenckert <i>et al.</i> (2006)c ³⁴	24 children. ā: 8[5–10]	Tetric Flow _e + Excite _e n = 22	No	No	Conventional	Experienced	yes	4.5	4.3	0	0
Anderson- Wenckert et al. (2006)d ³⁴	57 children. ā: 8[5–11]	Tetric Flow₀ + Prompt™ L-Pop™ n = 24	No	No	Conventional	Experienced	yes	0	0	0	0
Atieh M. (2008) ²⁷	87 children. ā: 5.5 ± 1.1[4–7]	Vitremer™ + Filtek™ Z250 (Open sandwich) n=64	No	No	Conventional	Experienced	yes	4.68	3.1	_	3.1
Ersin <i>et al.</i> (2008)a ³¹	126 children. ā: 7.6[6–8]	Ketac Molar n = 57	Ketac Conditioner	Ketac Molar Glaze	ART	Experienced	No	_	0.66	0.66	0.66
Ersin <i>et al.</i> (2008)b ³¹	126 children. ā: 7.6[6–8]	Ketac Molar n = 56	Ketac Conditioner	Ketac Molar Glaze	ART	Experienced	No	_	0.62	0.62	0.60
Topaloglu-Ak et al. (2009)a ³²	327 children. ā: 6.2 ± 0.5 [6,7]	Filtek _{DM} Z250 + Adper _{DM} Prompt _{DM} L-Pop _{DM} n = 210	No	No	ART	Experienced	No	68	20	_	12
Topaloglu-Ak et al. (2009)b ³²	327 children. ā: 6.2 ± 0.5[6,7]	$Filtek_{\text{\tiny DM}} \\ Z250 + Adper_{\text{\tiny DM}} \\ Prompt_{\text{\tiny DM}} \\ L-Pop_{\text{\tiny DM}} \\ n = 200$	Carisolv ₁₈	No	ART	Experienced	No	78	10	_	12
Alves dos Santos <i>et al.</i> (2009)a ¹¹	48 children. ā: 5.75[3–9]	Vitremer _™ n=12	Vitremer _™ Primer	No	Conventional	Experienced	Yes	0	33.3	25	25
Alves dos Santos <i>et al.</i> (2009)b ¹¹	48 children. ā: 5.75[3–9]	Freedom + Stae adhesive n = 13	No	No	Conventional	Experienced	Yes	0	46.15	30.76	46.15
Alves dos Santos <i>et al</i> . (2009)c ¹¹	48 children. ā: 5.75[3–9]	TPH _o Spectrum _o + Prime & Bond _o NT n=14	No	No	Conventional	Experienced	Yes	0	21.42	14.28	21.42
Carvalho <i>et al.</i> (2010)a ³⁷	232 children ā: 6.3[6,7]	GC Fuji IX n = 83	GC Fuji IX liquid diluted with a wet cotton ball	No	ART	Experienced	No	0.12	_	_	0.93

Study	Participants (number of children, average age and interval)	Materials (n)	Cavity conditioner (*)	Coat	Cavity form	Dentist experience	Rubber dam	Retention success rate	Marginal integrity success rate	Anatomic form success rate	Absence of recurrent caries success rate
Carvalho <i>et al.</i> (2010)b ³⁷	232 children ā: 6.3[6,7]	GC Fuji IX n = 72	GC Fuji IX liquid diluted with a wet cotton ball	No	ART	Experienced	Yes	0.93	_	_	0.91
Kotsanos et al. ³⁵	61 children. ā: 6.3 ± 1.60[3,5- 8]	Vitremer _™ n=83	Vitremer _™ Primer	"Finishing gloss"	Conventional	Experienced	Yes	_	0.95	0.96	0.99
Sengul <i>et al.</i> (2015)a ²⁰	41 children ā: 5.8 ± 0.9[5–7]	Beautiful n = 38	_	_	Conventional	Experienced	Yes	0.9	0.94	0.92	0.92
Sengul <i>et al.</i> (2015)b ²⁰	41 children ā: 5.8 ± 0.9[5–7]	GC Fuji II LC n = 32	GC Cavity Conditioner	No	Conventional	Experienced	Yes	0.9	0.9	0.94	1
Sengul <i>et al</i> . (2015)c ²⁰	41 children ā: 5.8 ± 0.9[5–7]	Valux Plus + Prime-Bond NT n = 40	_	_	Conventional	Experienced	Yes	0.93	0.95	0.93	0.98
Sengul <i>et al.</i> (2015)d ²⁰	41 children ā: 5.8 ± 0.9[5–7]	Dyract AP n=36	_	_	Conventional	Experienced	Yes	0.78	0.81	0.81	0.89

Table 1. Main results of the studies. (*) Cavity conditioner, referring only to glass ionomer materials.

95% CI								
	k	p +	LL	UL	Q	I^2		
Retention	27	0.879	0.803	0.928	260.4977***	90.02		
Marginal integrity	27	0.898	0.852	0.931	129.7594***	79.96		
Anatomic form	24	0.901	0.845	0.938	103.8451***	77.85		
Absence of recurrent caries	30	0.909	0.865	0.939	151.9184***	80.91		

Table 2. Mean success rates, 95% confidence intervals, and heterogeneity statistics. k = number of studies. p + = mean success rate. LL and UL: lower and upper limits of the 95% confidence interval for p +. Q = Cochran's heterogeneity Qstatistic; Q statistic has k - 1 degrees of freedom. I2 = heterogeneity index. ***p < 0.0001.

0.949), RMGIC ($p_+ = 0.956$), and open sandwich restoration ($p_+ = 0.950$), in comparison with resin-based material plus self-etching adhesion ($p_+ = 0.824$) and HVGIC ($p_+ = 0.671$). A marginally significant result was also found for anatomic form ($p_- = 0.051$), accounting for 51% of variance (Table 4 in Supplementary File 4), with the lowest success rate shown by HVGIC ($p_+ = 0.759$).

The form of the cavity was also associated with the success rates (p < 0.001), accounting for 46% of variance: the mean retention success rate was lower for ART ($p_+ = 0.649$) than for conventional cavity design ($p_+ = 0.936$). Similar results were found for marginal integrity (p = 0.040, $R^2 = 0.21$; Table 2 in Supplementary File 4), anatomic form (p = 0.001, $R^2 = 0.63$; Table 4 in Supplementary File 4), and absence of recurrent caries (p = 0.046, $R^2 = 0.16$; Supplementary Table 6 in File 4). The dentist's experience was significantly associated with retention success rates (p = 0.048; Table 4), although it only explained 7% of variance. More experienced dentists had better success rates than non-experienced ones ($p_+ = 0.895$ vs.0.554, respectively). Of the methodological variables analysed, assessor blinding was significantly associated with retention success rates (p = 0.028, p = 0.028,

Explanatory models. Although some of the moderators were significantly associated with retention success rates, none showed non-significant results in the model misspecification tests (Q_E and Q_W for meta-regressions and ANOVAs, respectively), suggesting residual heterogeneity among the success rates after including the moderator. Similar results were found for marginal integrity, anatomic form, and recurrent caries success rates (see Supplementary File 4). Therefore, multiple meta-regression models including the most relevant characteristics of the studies were applied to explain the variability in the different success rates.

The predictors included in the meta-regression models for explaining success rates were selected as a function of both statistical and practical significance achieved in the previous results of the ANOVAs and simple meta-regressions. A moderator variable was included in the model when the F statistic was significant and the F index was F was F with respect to retention success rates, four predictors were included: the sample size, the material (dichotomized as: 1 for resin-based material plus total-etching adhesion, RMGIC, and open sandwich restoration; and 0 for resin-based material plus self-etching adhesion and HVGIC), the form of the cavity (0: ART, and 1: conventional cavity design), and assessor blinding (0: no blinding, and 1: blinding).

Due to missing data in some variables, the number of studies included in the meta-regression was k = 27. The results are shown in Table 5. The full model showed a significant association with the retention success rates (p = 0.001), accounting for 45% of variance. However, once the other predictors were controlled for, none showed

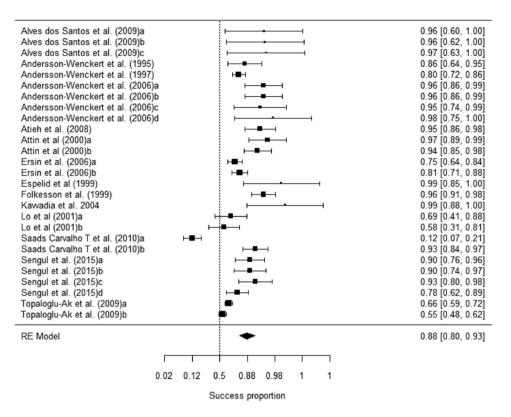


Figure 2. Forest plot of success rates at 24 months for retention (and 95% confidence intervals).

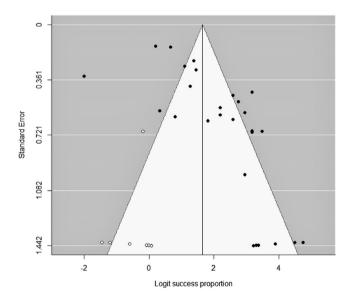


Figure 3. Funnel plot of the retention success-rate logits at 24 months. The seven white circles represent logits imputed using Duval and Tweedie's trim-and-fill method.

a significant association with the success rates. This may be due to collinearity among the predictors. Inspection of the bivariate correlations between the predictors showed a significant association between the form of the cavity and the type of material (r=0.66, p<0.001), as ART usually uses HVGIC material. When the form of the cavity was removed from the meta-regression model, the type of material (dichotomized) was significant (p=0.029) as was the full model, F (3, 23) = 7.34, p=0.001, accounting for 49% of the variance. Sample size and assessor blinding were not significant in the multiple meta-regression model.

The results of the multiple meta-regressions for marginal integrity, anatomic form, and recurrent caries success rates are shown in Supplementary Tables 7–9 in File 4. With respect to marginal integrity, two moderators were included in the model: cavity form and assessor blinding. There was a trend to significance for the full model

Moderator variable	k	$b_{\rm j}$	F	p	$Q_{\rm E}$	R^2
Mean age (years)	23	0.229	0.553	0.465	204.315***	0.03
SD of age (years)	11	1.193	1.848	0.207	46.612***	0.27
Sample size	27	-0.009	13.776	0.001	151.956***	0.37
Gender (% male)	16	-0.091	2.984	0.152	156.351***	0.29
Year of the study	27	-0.035	0.499	0.486	235.331***	0.03

Table 3. Results of the simple meta-regressions of continuous moderator variables on the retention success rate estimates. k = number of studies. bj = regression coefficient of each predictor. F = Knapp-Hartung's statistic for testing the significance of the predictor (the degrees of freedom for this statistic are 1 for the numerator and k - 2 for the denominator). p = probability level for the F statistic. QE = statistic for testing the model misspecification. $R^2 =$ proportion of variance accounted for by the predictor. ***p < 0.0001.

(p=0.051), with 22% of variance accounted for, while neither predictors were significant once the influence of each on the other was controlled for. Cavity form and assessor blinding were included in the meta-regression model for anatomic form success rates. A significant association was found for the full model (p=0.005) and 61% of variance was accounted for. In addition, the cavity form was significantly associated with anatomic form success rates (p=0.017) after controlling for assessor blinding. With respect to recurrent caries, three moderators were included in the meta-regression model: use of coat, cavity form, and assessor blinding. The full model was significant (p=0.007), with 83% of variance accounted for. Of the three moderators, only the use of coat was negatively associated with recurrent caries success rates (p=0.022).

Discussion

Since the FDA advised, in July 2010, that dental amalgam should not be used in children aged <6 years, due to its greater sensitivity to the potential toxic effects of mercury 67 , and the EU banned its use, from July 1, 2018, for the restoration of primary teeth, in children aged <15 years, and pregnant or breastfeeding women 68 , paediatric dentists need to know what the best alternative material for the restoration of primary teeth is. Therefore, this meta-analysis tried to answer the question: which tooth-coloured restoration material has the best clinical behaviour in proximal restorations of primary teeth at 24 months? We chose proximal restorations because they have the highest failure rate, especially when functional, due to the presence of antagonistic teeth 52 .

We studied the success rate at 24 months ought to the dropout rates of study subjects increase over time because there is a marked increase in the rates of physiological exfoliation, characteristic of childhood growth⁵³. Moreover, after that time many studies have reported a high level of failure, depending on clinical variables and patient related factors. In general, the annual failure rate was 17% for restorations in primary molars⁶⁹, although some studies recorded losses of around 50% at 24 months of follow up^{23,57}. The success rate for class II in primary teeth was 68% at 18 months⁷⁰ and 52 ´58% at 36 months⁷¹. This way, a study found that after a 7-year follow-up, only 1% of initial restorations completed the study⁷².

For better understanding of the results, the materials used in the studies analysed were divided into five groups: materials containing resin bonded with total etching (composite, giomers, compomer and fluid composite); resin-containing materials bonded with a self-etching adhesive (composite, compomer and fluid composite), RMGLC, HVGIC, and open sandwich technique (RMGIC as a base and composite as a restorative material). Regardless of the material used, retention of proximal restorations was the most affected, with 12.5% of restorations lost within 24 months of placement. Marginal integrity, conservation of the anatomical shape and the absence of secondary caries, in descending order, were affected to a lesser extent.

The success of a restoration depends on factors such as the material used, the state of the tooth, the experience of the operator and, the patient's collaboration. This last aspect is of paramount importance in paediatric dentistry, since children's behaviour largely determines the selection of the material and the technique to be used to restore a tooth, conditioning, finally, the wide variations in the success rate between the different materials and studies²¹. Unifying all the materials included in the study in materials that contain resin and those that do not, the meta-analysis showed that those containing resin had a higher success rate in the four clinical categories studied. RMGIC had the highest success rate followed by resin-based materials used with total etching and self-etch adhesives. The material with the lowest success rate was HVGIC. Although only retention was significant, the trend in all clinical categories studied (marginal integrity, anatomic form and recurrent caries) was the same.

A meta-analysis showed that RMGIC performed better than conventional GIC for class II restorations in primary teeth⁹. Another study also observed a better performance of RMGICs compared with conventional GICs and composites for class II primary teeth, arguing that RMGICs combine the best properties of both materials: on the one hand they have the good mechanical properties of composites and, on the other, the self-adhesive properties of GICs⁷³. Vitremer (3 M ESPE, St. Paul, MN, USA) was the RMGIC used in the largest number of studies included in our meta-analysis. Of the five studies, in four it was used together with Vitremer Primer (3 M ESPE, St. Paul, MN, USA), a light cure adhesive that contains, among other things, 2-hydroxyethyl methacrylate monomer (45–55%) and the copolymer of acrylic and itaconic acids (10–30%). The joint use of the Primer gives it a greater adhesive capacity and reduced sensitivity to the exchange of water with the surrounding environment by rapid photopolymerization⁷².

HVGIC showed, in our study, the worst retention rate (0.671), similar to other studies that found a 65% survival rate in multi-surface ART restorations using HVGIC⁷⁴ or failures in 30% of class II ART restorations during the first month using HVGIC⁵². A study that compared the use of HVGIC using ART versus a conventional cavity

Moderator variable			95% CI			
		p_+	LL	LU	ANOVA results	
-Material:						
Resin-based material plus total-etching adhesion	7	0.949	0.868	0.981		
Resin-based material plus self-etching adhesion Resin-modified Glass-ionomer cement (RMGIC) High-viscosity Glass-ionomer Cement (HVGIC)		0.824	0.672	0.914	F(4,22) = 4.22, p = 0.011	
		0.956	0.865	0.986	$R^2 = 0.36$ $Q_W(22) = 148.92, p < 0.001$	
		0.671	0.447	0.838		
Open Sandwich Restoration	1	0.950	0.639	0.995	7	
-Use of coat:					F(1,10) = 0.16, p = 0.699	
No	9	0.854	0.609	0.956	$R^2 = 0.0$	
Yes	3	0.904	0.474	0.989	$Q_{\rm W}(10) = 149.51, p < 0.001$	
-Use of cavity conditioner:					F(1,10) = 2.27, p = 0.163	
No	2	0.973	0.695	0.998	$R^2 = 0.03$	
Yes	10	0.826	0.605	0.937	$Q_{\rm W}(10) = 135.14, p < 0.001$	
-Use of rubber dam isolation:					F(1,22) = 2.25, p = 0.148	
No	14	0.847	0.726	0.920	$ \begin{array}{c} R(1,22) = 2.25, p = 0.148 \\ R^2 = 0.16 \\ Q_W(22) = 206.44, p < 0.001 \end{array} $	
Si	10	0.931	0.834	0.973		
-Cavity form:	F(1,25) = 24.76, p < 0.001					
Atraumatic restorative treatment (ART)	8	0.649	0.488	0.783	$R^2 = 0.46$	
Conventional cavity design	19	0.936	0.895	0.961	$Q_{\rm W}(25) = 138.88, p < 0.001$	
- Dentist experience:					F(1,25) = 4.34, p = 0.048	
Experienced	25	0.895	0.828	0.938	$R^2 = 0.07$	
Non-experienced	2	0.554	0.168	0.885	$Q_{W}(25)=232.264, p < 0.001$	
-Type of study:	1				-1	
Noncontrolled trial	3	0.892	0.614	0.977	F(2,24) = 0.25, p = 0.783	
Nonrandomized controlled trial	9	0.899	0.768	0.961	$R^2 = 0.09$	
Randomized controlled trial	15	0.854	0.718	0.931	$Q_{\rm W}(24) = 197.82, p < 0.001$	
-Random assignment:					F(1,25) = 0.55, p = 0.465	
No/Incorrect	12	0.897	0.792	0.952	$R^2 = 0.16$	
Correct	15	0.851	0.716	0.929	$Q_{\rm W}(25) = 197.88, p < 0.001$	
-Triple-blind					E(1.25) — 5.48 p — 0.029	
No	11	0.934	0.859	0.971	$F(1,25) = 5.48, p = 0.028$ $R^2 = 0.32$	
Yes	16	0.805	0.674	0.892	$Q_{\rm W}(25) = 176.25, p < 0.001$	
-Reporting bias:					F(1,25) = 0.82, p = 0.374	
No	24	0.867	0.779	0.924	$R^2 = 0.08$	
Yes	3	0.935	0.726	0.987	$Q_{\rm W}(25) = 236.27, p < 0.001$	
-Financial source:					E(1.15) — 1.07.6—0.217	
Private or mixed	5	0.807	0.482	0.949	$F(1,15) = 1.07, p = 0.317$ $R^2 = 0.0$	
Public	12	0.909	0.785	0.965	$Q_{\rm W}(15) = 157.82, p < 0.001$	

Table 4. Results of the weighted ANOVAs of qualitative moderator variables on the retention success rates. k = number of studies. p + = mean success rate. LL and LU = lower and upper 95% confidence limits for p_+ . F = Knapp-Hartung's statistic for testing the significance of the moderator variable. QW = statistic for testing the model misspecification. $R^2 = \text{proportion of variance accounted for by the moderator}$.

technique concluded that, for HVGIC, there is a greater risk with ART cavities than with conventional cavities in primary tooth decay treatments, and success rates in classes II are worse than in class I^{75} . This association between the poor results of ART and the poor clinical performance of HVGIC is strongly supported by our results, in which the bivariate correlations between predictors revealed a strong relationship (r=0.66, p<0.001) between the cavity form and the type of material. This may be due to the peculiarities of the ART technique, which uses HVGIC as a restorative material and does not allow complete isolation, meaning saliva contamination of the operative field is very frequent⁷⁶ and the survival of multi-surface restorations could be more dependent on the material, operator and control of the operative field than single-surface restorations⁵⁷. However, in a randomized controlled study 10 year follow-up to evaluate the durability and clinical performance of a HVGIC (processed with a resinous coating) compared with a micro filled composite resin in conventional class I y II cavities, in permanent teeth isolated with cotton rolls and suction devices, no significant differences were found for both restorative materials in terms of marginal adaptation, anatomical form, secondary caries, postoperative sensitivity, surface texture, and retention. The HVGIC could be also considered a good alternative to amalgam⁷⁷.

Although we found a higher retention success rate when the dentist was experienced, we found no influence of the type of isolation. In "in vitro" studies, adhesion to enamel and dentin of materials containing composites are very sensitive to salivary contamination, although the results of "in vivo" studies are unclear. A systematic

Predictor variable	$b_{\rm j}$	t	p	Model fit
Intercept	-1.942	-0.89	0.384	F(4, 22) = 6.62, p = 0.001
Sample size	-0.0002	-0.06	0.956	$R^2 = 0.45$
Type of material	0.831	1.51	0.146	$Q_{\rm E}(22) = 114.86, p < 0.0001$
Cavity form	1.558	1.68	0.108	
Assessor blinding	-0.11	0.19	0.845	

Table 5. Results of the multiple meta-regression model applied on the retention success rates, taking as predictors the sample size, the type of material (dichotomized), the cavity form, and the assessor blinding (k=27). b_j = regression coefficient of each predictor. t = statistic for testing the significance of the predictor (with 22 degrees of freedom). p = probability level for the t statistic. F = Knapp-Hartung's statistic for testing the significance of the full model. Q_F = statistic for testing the model misspecification.

review found that, in the longevity of direct dental restorations made with a tooth-coloured material in primary teeth, the use of a rubber dam did not influence the results compared with the use of roll of cotton together with a saliva ejector⁷⁸. A meta-analysis concluded that there are few studies with a very low quality of evidence on the advantages of using the rubber dam compared to cotton rolls together with a saliva ejector on the survival of restorations and neither, the previous application of cavity conditioner nor the final application of coating on the glass ionomer, influenced the success of the clinical variables studied⁷⁹.

Our results showed that, of all the methodological variables used, the type of trial, randomization, reporting bias and the source of funding did not influence the retention, marginal integrity, anatomic form and absence of recurrent caries success-rates, indicating that the type of study did not influence the results of the different materials and supports our decision not to use quality scales, where the type of study is decisive in the final score, to decide the inclusion of the works in our meta-analysis, but include all studies that met the inclusion criteria considering as an independent study each of the materials used or each of the different experimental conditions used with the same material.

Evaluator blinding was important in determining the success of the restoration in the four clinical criteria evaluated in the opposite direction as expected, since when the evaluator knew the material the degree of success measured was lower than when they did not. The influence that we have observed in the triple blind indicates that in the next studies that are carried out, the evaluator must be masked. Meta-regression of each moderator variable showed only the sample size had a significant negative association with the estimated retention success rate indicating that, as the sample size increased, the retention success rate fell. One of the limitations of the studies included in our meta-analysis was the small sample size [median 56, min-max 12–210]: studies were initiated with a small sample size with a high loss rate, which was very high at 24 months. Multiple meta-regressions to determine the predictors that explained the success of proximal restorations showed a similar behaviour for retention, marginal integrity, anatomic form, and recurrent caries success rates. All included the cavity form and assessor blinding as predictors. In addition, the sample size, the type of material and the use of coat were predictors of the index of retention.

A possible bias is the different criteria used in the studies to assess the clinical performance of the restorations. Thirteen used the various modifications of the USPHS criteria, one study used the USPHS criteria plus ART criteria, one study used the FDI criteria and one study used an own system. As there may be differences in the assessment of success depending on the criteria used, and the lack of sensitivity of the ART criteria in detecting improvements in the clinical performance of the materials currently used for dental restorations⁸⁰, we unified the criteria used in the selected articles into four categories: retention, marginal integrity, anatomic form and absence of recurrent caries. This enabled comparison of the studies and elimination of the bias that the use of different evaluation systems could introduce.

After RMGIC, the material that presented the best results was the open-type sandwich method followed by resin-containing materials adhered with the total etching technique. The sandwich method, which uses RMGIC as a cavitary base material and composite as a surface material, seems to have the advantages of both materials. However, only one study was included in this meta-analysis, and therefore further studies are required to determine whether the good results are maintained. Likewise, studies that combine the speed and simplicity of the ART technique with RMGICs, which had the best clinical behaviour in proximal restorations at 24 months, are required.

In conclusion, the null hypothesis of our meta-analysis was disproved, as the index of success of proximal restorations in primary teeth at 24 months was found to depend on the type of coloured material used. The materials with the highest success rates were those that contained resin. Of these, RMGIC performed best. The highest failure rate was for HVGIC and with the cavity made using ART, which were significantly correlated. The shape of the cavity, triple blinding and the experience of the operator had the most influence on the success rates of proximal restorations.

Data availability

All data generated or analysed during this study are included in this published article (and its Supplementary Information files).

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Author contributions

All authors contributed to the study conception and design. The literature search was made by Antonio José Ortiz Ruiz and Nuria Pérez Guzmán. The statistical analysis was made by Julio Sánchez Meca and María Rubio Aparicio. The article was written by Antonio José Ortiz Ruiz, Nuria Pérez Guzmán, María Rubio Aparicio and Julio Sánchez Meca. All authors read and approved the final manuscript

Competing interests

The authors declare no competing interests.

Additional information

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