Scientific Article

Evidence-based Assessment of Tooth-colored Restorations in Proximal Lesions of Primary Molars

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Abstract: *The purpose of this study was, using evidence-based dentistry, to compare the successes of glass ionomer cement (GIC), resin-modified GIC (RmGIC), composite resin (CR), and polyacid-modified composite resin (PAMCR) in primary molar proximal lesions. Methods: The PICOT question was: P: in primary molar proximal lesions; I: does the use of 1 material (GIC, RmGIC, CR, or PAMCR); C: compared with the remaining materials; O (Outcome): result in higher success rates; T: when followed for at least 1 year? Relevant articles (256) were identified from databases then sieved by titles, abstracts, and full texts. Following exclusions, 36 clinical trials—including 25 randomized clinical trials (RCTs)—remained. Extracted data were meta-analyzed. Results: GIC restorations had a significantly (P<.05) lower likelihood of success than RmGIC and CR restorations. Overall success rates were: (1) GIC (691 restorations)=75%; (2) RmGIC (276)=89%; (3) CR (620)=83%; (4) PAMCR (596)=87%. Mean success rates did not differ significantly (P>.05): (1) GIC (6 studies)=65±34%; (2) RmGIC (3 studies)=93±7%; (3) CR (7 studies)=85±12%; and (4) PAMCR (8 studies)=90±10%. Conclusions: Few articles were available to determine the best material. Recognizing material improvements since 1990, earlier data may be noncomparable. RmGIC had the highest success rates, but fewest studies and fewest restorations; only one product was assessable. Prospective RCTs should be of at least 5 years' duration to determine correctly the success rate of Class II restorations in primary molars. (Pediatr Dent 2007;29:8-15)*

KEYWORDS: EVIDENCE-BASED DENTISTRY, TOOTH-COLORED RESTORATIONS, PROXIMAL LESIONS, PRIMARY MOLARS

Under increasing esthetic demands, amalgam has given way to tooth-colored materials for restoring proximal lesions in primary molars. With many such materials available, choice is difficult for the clinician and new materials may be introduced before existing materials are evaluated fully. Four types of direct tooth-colored restorative materials currently used in children are: (1) glass ionomer cements (GICs); (2) resin-modified glass ionomer cements (RmGICs); (3) composite resins (CRs); and (4) polyacid-modified composite resins or compomers (PAMCRs).

Previously, material choice for many dentists was based on personal preferences or experience; clinical approaches now favor evidence-based decisions. The American Dental Association defines evidence-based dentistry (EBD) as "an approach to oral health care that requires the judicious integration of systematic assessments of clinically relevant scientific evidence, relating to the patient's oral and medical condition and history, with the dentist's clinical expertise and the patient's treatment needs and preferences."[1] The preferred evidence in evidence-based practice is from prospective randomized controlled clinical trials (RCTs). Conducting RCTs on dental materials, however, is constrained by: (1) time; (2) cost; and (3) ethics. Therefore, to determine material choice, a clinician can study current peer-reviewed publications or published reviews. If guidelines are unavailable, the practice of EBD conducted using the best available evidence can assist the clinician to answer the question scientifically.

The present study investigated whether recommendations for the use of certain tooth-colored restorative materials in proximal lesions of primary molars could be made based upon an evidence-based study of the pediatric dental literature. The aims of this study were twofold:

1. to use the principles of evidence-based dentistry to compare the successes of GIC, RmGIC, CR, and PAMCR restorations in proximal lesions of primary molars; and
2. to make recommendations on material selection for proximal lesions in primary molars.

Methods

The authors have previously described the 6 steps in conducting an evidence-based study.[2] The research question was: Which direct tooth-colored restorative material (GIC,

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Table 1. EXCLUSION CRITERIA APPLIED DURING SEARCH STRATEGY

SEARCH STRATEGY STEPS	EXCLUSION CRITERIA APPLIED
INITIAL SEARCH ON DATABASE	1. Articles not in English 2. Animal studies 3. Duplicate articles
PRELIMINARY SIEVE BY EXAMINING TITLES	1-3 plus: 4. All other teeth except primary molars 5. All other uses of tooth-colored restorative materials except in direct restorations 6. Amalgam, black copper cement, gallium, silver cermet, sandwich restorations
SECONDARY SIEVE BY EXAMINING ABSTRACTS	1-6 plus: 7. All other classes of restorations except Class II or box preparations 8. Not pertaining to clinical performance, success rates, survival time 9. Atraumatic/alternative restorative technique (ART) 10. Effects of different cavity preparations, caries removal methods, placement technics 11. Effects of sealants, adhesives, conditioners, etching technics 12. Bond strength, cariostasis, fluoride release, mutans streptococci
TERTIARY SIEVE BY EXAMINING FULL TEXTS	1-12 plus: 13. All other studies except clinical trials 14. Follow up period less than 1 year 15. Articles without full text 16. Articles of same study with shorter follow-up 17. Wear

RmGIC, CR, or PAMCR) has the highest success rate in restoring proximal lesions in primary molars? The PICOT question was:

- P (population): in human primary molars with proximal lesions;
- I (intervention): does the use of one tooth-colored restorative material (GIC, RmGIC, CR, or PAMCR);
- C (comparison): compared with the remaining materials;
- O (outcome): result in higher clinical success rates;
- T (time): when followed for at least 1 year?

A search for evidence-based guidelines or policy statements on the selection of tooth-colored restorative materials in primary teeth was conducted. A search for relevant systematic reviews or meta-analyses in secondary evidence-summary publications and collaborative research networks was done to check if the answer to the question was already available.

Search tools within electronic databases were used to locate all citations on tooth-colored restorative materials, primary molars, and pediatric restorative dentistry. Journal articles were sieved by examining: (1) titles; (2) abstracts; and (3) complete texts. Exclusion criteria were applied in each sieve to narrow the search (Table 1). In a final search for relevant articles, the exclusion criteria were applied to articles cited in the reference lists of the remaining articles. These additional articles, together with the original list of articles remaining after the 3 sieves, formed the final list.

Articles included after examining the full text were appraised; data were extracted and article quality was assessed using a data extraction and critical appraisal form.[3] Articles were ranked on hierarchical strength of evidence as: (1) randomized controlled clinical trials (RCTs); (2) controlled clinical trials (CCTs); or (3) clinical trials without control and randomization (CTs). The RCTs were defined as prospective clinical studies with random allocation of study and control groups and all cases accounted for. The CCTs were also prospective clinical studies, but without random allocation of study and control groups. The CTs were uncontrolled prospective clinical studies examining a single type of restorative material.

Data reported in the studies were used to compute the percent success rates of restorations. Some studies did not report the number of successful or failed restorations, reporting instead individual ratings based on clinical observations using the modified Ryge criteria.[4] These studies were excluded, since a failed restoration could have one or more failure ratings on these criteria. Data were entered into RevMan 4.2 (Cochrane Collaboration, Oxford, UK), a Windows-based software product designed for Cochrane reviews and meta-analyses.[5]

Meta-analyses were conducted using direct and indirect techniques. The direct technique directly compared any 2 materials (GIC, CR, RmGIC, and PAMCR) in the same study. Proportional data from studies were combined as a common odds ratio (COR) by pooling the success rates from both trials. The implications of the COR were:

1. COR>1=Test material was significantly more success ful than control material.
2. COR<1=Control material was significantly more suc cessful than test material.
3. COR=1=The 2 materials did not differ.[6]

The indirect technique compared materials by pooling and analyzing data selected from relevant arms of different studies. The overall success rate for each material was computed as the sum of successful restorations divided by the sum of restorations placed in all studies. The mean (±SD) success rates were derived from the individual success rates in studies and compared statistically (student's unpaired *t* test). For all statistical tests, the level of significance was set at $P<.05$.

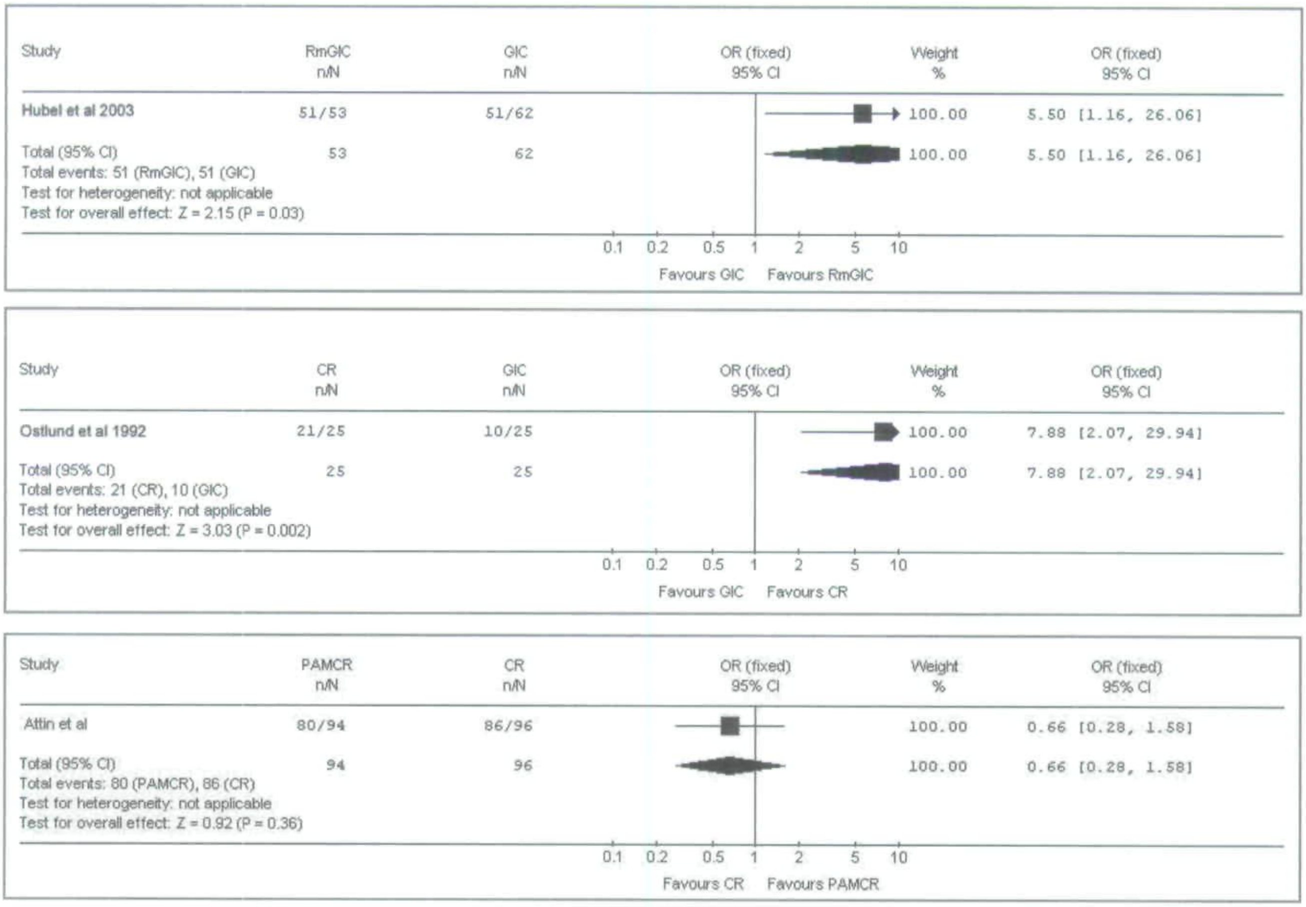
Results

Initial database searches. No guidelines for selecting tooth-colored restorative materials for proximal lesions in primary molars were found, and systematic reviews and meta-analyses were unavailable. The OVID health sciences databases provided access to MEDLINE and CINAHL databases and EBM Reviews. The latter includes the: (1) Cochrane Database of Systematic Review; (2) Database of Abstracts of Reviews of Effectiveness; (3) Cochrane Central Register of Controlled Trials; and (4) ACP Journal Club.[7,8] Keywords, synonyms, and search strings were entered into the databases. When all 4 materials were combined with "pediatric restorative dentistry" or "tooth-colored restorations," 45,569 citations resulted. These were reduced to 256 citations when "primary molar(s) or deciduous molar(s)" were combined.

Results of the search strategy and evaluation of data. The 256 citations were reduced to 193 articles by excluding: (1) animal studies; (2) non-English articles; and (3) duplicates. The 193 articles were screened by title (preliminary sieve): 55 articles met the exclusion criteria, and 138 articles remained. Abstracts of the 138 articles were screened (secondary sieve), and 64 articles were excluded; 74 articles remained. Five articles could not be located, leaving 69 articles for the first appraisal, ranking, and tertiary sieving. Forty-two articles then met the exclusion criteria (Table 1), and 27 articles remained. Bibliographies in these articles revealed 9 articles previously unidentified. Thirty-six (27+9) articles—comprising 25 RCTs and 11 non-RCTs (1 CCT, 10 CTs)—were relevant to the PICOT question. Of the 36 articles, 15 studies (11 RCTs, 1 CCT, 3 CTs) were excluded due to lack of data, differing outcome measurements, or because other restorations were combined with proximal restorations. The distribution of the remaining 21 studies (14 RCTs, 7 CTs)[9-29] by length of follow-up, material type, and product is shown in Table 2. Of these, 19 studies were followed for 1 to 3 years and 2 studies were followed for 4 or 6 years. With the exception of RmGIC, all materials had at least 5 products tested (Table 2). Data from the 21 studies were extracted and meta-analyzed.

Table 2. DISTRIBUTION OF 21 STUDIES USED IN META-ANALYSES BY LENGTH OF FOLLOW-UP, MATERIAL TYPE, AND PRODUCT

Length of follow-up (ys)	Glass ionomer cement (6 studies)	Resin-modified glass ionomer cement (3 studies)	Composite resin (7 studies)	Polyacrylic acid-modified composite resin (8 studies)
1	Fuks et al[23] (Fuji Ionomer)	-	Paquette et al[9] (Profile, Visio Fil)	Trummler et al[28] (Ariston pHc)
2	Kilpatrick et al[14] (Ketac Fil)	-	Oldenberg et al[11] (H-120, Sybralloy) Barr-Agholme et al[12] (P-30)	Gross et al[19] (Hytac, Dyract) Duggal et al[20] (Dyract) Kavvadia et al[22] (F 2000) Andersson-Wenckert et al[25] (Dyract) Papagiannoulis et al[27] (Dyract)
3	Ostlund et al[13] (Chem Fil II) Qvist et al[15] (Ketac Fil) Hubel and Mejare[21] (Fuji II) Rutar et al[29] (Fuji IX)	Espelid et al[16] (Vitremer) Hubel and Mejare[21] (Vitremer) Folkesson et al[26] (Vitremer)	Ostlund et al[13] (Occlusin) Attin et al[18] (TPH Spectrum)	Marks et al[17] (Dyract) Attin et al[18] (Compoglass)
4	-	-	Oldenberg et al[10] (Fuji Fil, X-55)	-
6	-	-	Varpio[24] (Concise)	-



Figures 1a-c. Odds ratios for direct comparisons of tooth-colored restorations.

Meta-analyses using the direct technique. Direct meta-analyses are shown in Figures 1(a-c) using the plotting capability of RevMan 4.2.[5] The fixed effect model was chosen, assuming a single average effect (ie, clinical success) and that all the studies came from a population of studies measuring this fixed effect.[5]

The performance of Class II GIC and RmGIC restorations over 3 years was compared in 40 child patients regularly attending the pediatric dentistry clinic of the Eastman Dental Institute, Stockholm, Sweden.[21] The proportions of successful restorations were: (1) RmGIC=51/53 (96%); (2) GIC=51/62 (82%). The OR was 5.50 (95% CI=1.16-26.06; *P*=.03), indicating that the RmGIC restorations were significantly more successful (5.50 fold) than GIC restorations (Figure 1a).

Class II amalgam, CR, and GIC restorations were compared over 3 years in 50 child patients in a public dental clinic in Sweden.[13] The proportions of successful restorations were: (1) CR=21/25 (84%); and (2) GIC=10/25 (40%). The OR was 7.88 (95% CI=2.07-29.94; *P*=.002), indicating that the CR restorations were significantly more successful (7.88 fold) than GIC restorations (Figure 1b).

Class II PAMCR and CR restorations were compared in the primary molars of children in Germany.[18] The proportions of successful restorations were: (1) PAMCR=80/94 (85%); and (2) CR=86/96 (89%). The OR was 0.66 (95% CI=0.28-1.58; *P*=.36), indicating that PAMCR restorations were less successful (but not significantly) than CR restorations (Figure 1c).

Homogeneity tests were inapplicable, since for each pair of comparisons the data were taken from only one study. Meta-analyses comparing PAMCR with CR, CR with RmGIC, and PAMCR with RmGIC could not be done due to a lack of published studies.

Meta-analyses using the indirect technique. The overall and mean success rates of the 4 materials are shown in Figures 2 and 3, respectively. Each figure shows the distribution of RCTs and non-RCTs individually and in combination. The distribution of studies and total restorations meta-analyzed were as follows:

1. GIC=6 studies (4 RCTs, 2 non-RCTs)[13-15,21,23,29] providing 691 restorations;
2. RmGIC=3 studies (2 RCTs, 1 non-RCT)[16,21,26] providing 276 restorations;

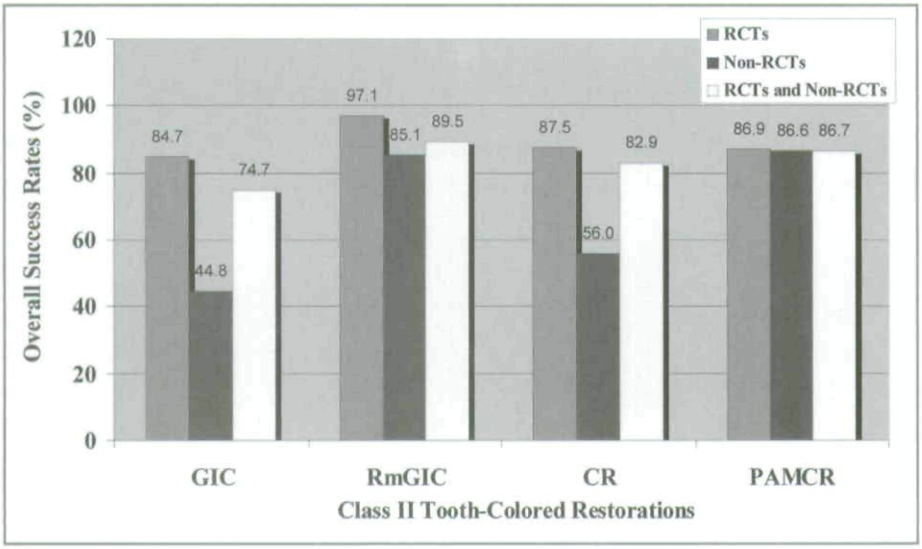


Figure 2. Comparison of overall success rates of Class II tooth-colored restorations in primary molars.

3. CR=7 studies (6 RCTs, 1 non-RCT)[9-13,18,24] providing 620 restorations; and
4. PAMCR=8 studies (5 RCTs, 3 non-RCTs)[17-20,22,25,27,28] providing 596 restorations.

The overall success rates for restorations in the RCTs and non-RCTs in combination were: (1) GIC=75%; (2) RmGIC=89%; (3) CR=83%; and (4) PAMCR=87% (Figure 2). Overall success rates for restorations in non-RCTs were lower than for RCTs for 3 materials (GIC=45%; RmGIC=85%; CR=56%) and similar for PAMCR (86%; Figure 2).

The mean (±SD) success rates for restorations in the RCTs and non-RCTs in combination were: (1) GIC=65±34%; (2) RmGIC=93±7%; (3) CR=85±12%; and (4) PAMCR=90±10% (Figure 3). These values did not differ with statistical significance (P>.05). The mean (±SD) success rates for restorations from RCTs alone were: (1) GIC=72±22%; (2) RmGIC=97±1%; (3) CR=88±5%; and (4) PAMCR=88±11%. These values also did not differ with statistical significance (P>.05).

Discussion

Meta-analyses are subject to several biases. Ideally, only RCTs should be used. Nonrandomized trials, however, were included in the present study due to a lack of RCTs. Publication bias may occur, reflecting the greater likelihood of studies with statistically significant or directionally positive results being reported compared to those with null or nonsignificant results.[30] Limiting studies to those in English may omit relevant studies, producing language bias. The search for studies should be as comprehensive as possible to limit bias. In the present study, 3 large databases, including MEDLINE, were used. Articles published prior to the mid 1960s do not appear in MEDLINE searches. Since studies on tooth-colored restorations appeared predominantly after 1970, database retrieval was unaffected.[31] In the present study, articles without "primary/deciduous molars" in the title, abstract, or keywords, may have been excluded initially. Articles with vague titles or titles not reflective of content may also have been excluded or misclassified. For an unbiased meta-analysis, the numbers of trials and restorations excluded must not be so large as to affect the analysis. In the present study, bias was possible since 15 of 36 (42%) studies were excluded due to lack of data.

The differing success rates reported in studies cannot be attributed solely to material performance. Studies varied in follow-up length, with restorations followed for longer periods having lower success rates. Studies assessing older tooth-colored restorative materials had a higher failure rate than those developed more recently, suggesting improvements in materials and clinical techniques over time. Consequently, the meta-analyses in the present study may not reflect the performance of current products.

Wide variations in success rates for the same type of restorative material could be attributed to differing clinical performances of different products. In the present study, all materials with the exception of RmGIC had at least 5 products tested. Restorations placed under local or general anesthesia might perform better than those placed without anesthesia due to better control during treatment. Restorations placed under rubber dam isolation, compared with those placed

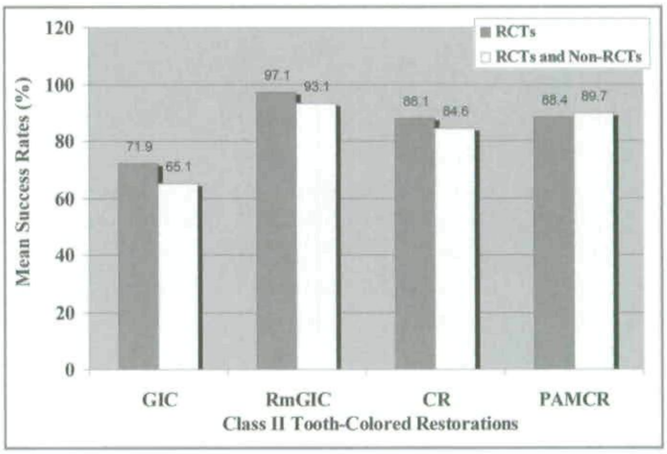


Figure 3. Comparison of mean success rates of Class II tooth-colored restorations in primary molars.

without isolation, could be expected to perform better due to moisture control. Better performance might also be expected from conventional cavity preparations with retentive features compared to those without retention.

Not all studies examined accounted for all restorations placed at baseline. To analyze the data similarly across studies, the number of successful restorations was calculated by subtracting the number of failures from the number placed. Therefore, an overestimation of success rates was possible as restorations in teeth extracted for orthodontics or pulpal pathology, and those lost to follow up, were considered successful.

The RmGIC restorations were significantly more successful than GIC restorations (OR=5.50; $P<.05$). This performance of RmGIC may reflect the dual setting mechanism that provides more complete hardening and higher fracture toughness, and also the higher flexural and tensile strengths and lower modulus of elasticity, than conventional GIC.[32-33]

The CR restorations were significantly more successful than GIC restorations (OR=7.88; $P<.05$). In the study by Ostlund et al, moisture contamination was minimized using rubber dam isolation.[13] Excellent moisture control is required during CR placement to prevent contamination of the adhesive surface, which can result in poor bonding and microleakage. With such moisture control, the superior physical and mechanical properties of CR over those of conventional GIC may dominate.

In comparing success rates of PAMCR and CR restorations, Attin et al reported no significant differences.[18] The mechanical properties of PAMCR such as tensile strength, flexural strength, and wear resistance may be superior to those of GIC but inferior to those of CR.[34-35] Compared with CR, however, PAMCR is readily handled and less hydrophobic and releases fluoride which may offset the poorer physical properties of PAMCR.

Using both direct and indirect meta-analyses, GIC restorations were the least successful and RmGIC restorations were the most successful. Of the 4 materials, the fewest studies (N=3) and fewest restorations (N=276) were assessed for RmGIC. Therefore, a chance finding cannot be excluded. Of note, the 3 studies[16,21,26] on RmGIC all used Vitremer (3M, St Paul, Minn), so the superior clinical performance may be attributed to this product only and not generalizable to all RmGIC products.

The low success rate of GIC restorations may reflect the low fracture toughness and flexural strength of GIC.[36] Conventional GICs are brittle and prone to bulk fracture.[32] The marginal ridges of Class II restorations receive considerable occlusal forces, which may contribute to the high failure rate of GIC restorations. The CR and PAMCR restorations had comparable success rates; higher than GIC but lower than RmGIC restorations. Recurrent caries has been reported as the main cause of failure for CR and PAMCR restorations.[13,17-20,37,38] The RmGIC restorations had the highest success rate, attributed to the superior physical and mechanical properties of RmGIC compared to conventional GIC and fluoride release.[32-39] Even though the physical properties of RmGIC may not match those of CR and PAMCR, Class II RmGIC restorations appeared to withstand the occlusal forces on primary molars for at least 1 year. No significant differences ($P>.05$) were found in the mean success rates (combined or RCTs alone) of the 4 materials. This may reflect the few studies of proximal restorations of primary molars available for meta-analyses.

Critical appraisal of evidence is important in determining the validity and relevance of studies. The quality of the RCTs evaluating success rates of tooth-colored restorations in primary molars was deemed to be good; most studies reported randomized allocation of test and control groups. Not all studies, however, accounted for all restorations placed and for those lost to follow-up. The "blinding" of patients and researchers to reduce bias was impossible due to differing material characteristics and placement procedures.

Few RCTs directly comparing tooth-colored restorations in primary molars were found, and there were no studies directly comparing RmGIC and PAMCR. The T (time) in the PICOT question used in the present study was set at a minimum of 1 year to include most studies. Primary molars exfoliate approximately 7 to 9 years after eruption, leading to the recommendation that follow-up studies should be at least 5 years in duration.[40] Studies on RmGIC restorations using several different manufacturers' products are needed to confirm the superior clinical performance noted in the present study. Meta-analyses of RCTs of at least 5 years duration are also needed.

Conclusions

An evidence-based study of 4 direct tooth-colored restorations in proximal lesions of primary molars was conducted, based on 36 studies (25 randomized clinical trials, 1 controlled clinical trial, and 10 clinical trials without control and randomization) identified as relevant to the PICOT question. Twenty-one studies (14 RCTs, 7 CTs) provided data suitable for meta-analyses, from which it was concluded that:

1. There were few appropriate articles to determine the best material for proximal lesions in primary molars. Recognizing material improvements since 1990, earlier data may not be comparable.
2. The answer to the PICOT question was: In human primary molars with proximal cavities, the use of resin-modified glass ionomer cement (RmGIC)—compared with glass ionomer cement, composite resin, and polyacid-modified composite resin—resulted in the

highest clinical success rates when followed for at least 1 year.

3. The RmGIC had higher clinical success rates than the other materials, but RmGIC had the fewest studies and restorations, and only 1 product was assessable.
4. Prospective RCTs should be of at least 5 years' dura tion to correctly determine the success rate of Class II restorations in primary molars.

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Abstract of the Scientific Literature

Third Molar Eruption After Early First Molar Loss

The aim of this study was to evaluate whether early loss of a permanent first molar has an effect on the development of the permanent third molars in the same quadrant. Materials consisted of panoramic radiographs and dental casts of 165 adolescents with early loss of a permanent first molar on one side. Third molar development on the extraction side was evaluated and the contralateral side was used as controls. Statistical analysis showed no significant sex differences for the formation stage of third molars. Therefore, data from both sexes were pooled. No significant differences were found in the developmental stages of the third molars between the various extraction quadrants in the same jaw and between those in the maxilla and mandible. Significant differences were found in developmental stages and eruptive conditions of the third molars between the extraction and control sides. Third molar development on the extraction side was significantly accelerated compared with contralateral teeth. Researchers concluded that early loss of the permanent first molars may have an accelerating effect on the development of third molars on the extraction side compared to contralateral teeth. ***Comments:*** *Third molars may erupt earlier if the permanent first molar is extracted in the same quadrant. Further, the developmental and eruptive conditions of third molars after early loss of first molars should be observed carefully by clinicians. RKY*

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