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ORIGINAL SCIENTIFIC ARTICLE

Clinical performance of Class II resin composite restorations in primary molars with or without pulpotomy: a prospective 24-month clinical study

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Abstract

Purpose To evaluate the clinical performance of Class II resin composite restorations in primary molars following pulpotomy and to compare them with Class II composite restorations in non-pulpotomised primary molars over 24 months.

Methods This prospective within-patient controlled study included healthy children aged 4–8 years with at least one primary molar requiring a Class II resin composite restoration with pulpotomy and one without pulpotomy. Restorations were placed under rubber dam isolation using a fifth-generation adhesive and resin composite. NeoMTA® was used for pulpotomies. Clinical evaluation was performed at 12 and 24 months by a blinded examiner using modified 'USPHS criteria'. Cross-sectional comparisons were performed using Chi-square or Fisher's exact tests, whilst longitudinal changes were analysed using the McNemar–Bowker test ($p < 0.05$).

Results Forty children (80 teeth) were enrolled initially. At 12 months, 37 children (74 teeth) were evaluated, whilst 32 children (64 teeth) completed the 24-month recall. Most restorations in both groups remained clinically acceptable throughout the study period. Marginal integrity was significantly lower in pulpotomised teeth at 12 months ($p = 0.003$) and at 24 months ($p = 0.011$). No statistically significant differences were observed for marginal discoloration, surface texture, wear, postoperative sensitivity, or recurrent caries ($p > 0.05$). Longitudinal analysis demonstrated significant deterioration in marginal integrity over time in the pulpotomy group ($p = 0.041$).

Conclusions Resin composite restorations in primary molars showed acceptable performance in both groups. However, restorations in pulpotomised teeth demonstrated reduced marginal integrity after 24 months.

Keywords Primary molars · Pulpotomy · Resin composite · Class II restoration · Clinical study

Introduction

According to the Global Burden of Disease study in 2017, more than 5.3 million children worldwide have cavitated caries lesions in their primary teeth (GBD 2017; WHO 2019). Clinical approaches for managing deep carious lesions in posterior primary teeth with possible pulp involvement include pulp therapies (direct/indirect pulp capping, pulpotomy, pulpectomy), depending on pulp status, aiming to avoid extraction and maintain the tooth asymptomatic, pathology free and functional until its natural exfoliation (Duggal et al. 2022).

Current guidelines of both the European and American Academies of Paediatric Dentistry (Duggal et al. 2022; AAPD 2024) recommend the treatment of carious primary molars by removing carious tissue and restoring Class II cavities, either with a) compomer or hybrid and bulk-fill composite resin, or a b) preformed metal crown (PMCs). The guidelines state that PMCs are indicated when "more than two surfaces are affected or when caries on one or two surfaces is extensive" (AAPD 2024). However, a significant disadvantage of PMCs is that additional sound tooth structure typically needs to be removed during tooth preparation, although the use of Hall technique has negated this step and aesthetics may not always be acceptable to parents or young

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patients (Innes et al. 2015). In addition, in cases involving pulpotomy, full coronal coverage is generally recommended to maximise the long-term success of the treated tooth. Aesthetic alternatives to PMCs, such as zirconia and polymer-based crowns, have been introduced primarily to address aesthetic concerns; however, current guidelines indicate that the supporting evidence for their use in primary posterior teeth remains limited (Chavhan et al. 2026; Al-Haj Ali 2025; AAPD 2025).

Recent studies have shown that teeth restored with PMCs are less likely to fail or cause pain long-term, compared to restorations (Duggal et al. 2022). On the other hand, resin composite restorations are less invasive, and successful adhesion to primary tooth structures can be achieved when combined with appropriate bonding agents and procedures. However, technique sensitivity and the reduced bond strength to primary enamel must be considered (Ghajari et al. 2020; Duggal et al. 2022). Considering the above, it appears that resin composite may be used to restore remaining tooth structure in Class II cavities after pulpotomy treatment in primary molars (Ghajari et al. 2020). However, existing studies have short follow-up periods and often controversial methodologies (Duggal et al. 2022).

Evidence directly comparing intracoronal resin composite restorations in pulpotomised and non-pulpotomised primary molars within the same patient remains limited.

Therefore, the objectives of this 24-month prospective within-patient clinical study were:

1. To evaluate the success rate of Class II resin composite restorations placed in primary molars following pulpotomy treatment.
2. To compare the clinical performance and success rate of Class II resin composite restorations in pulpotomised primary molars with those placed in non-pulpotomised primary molars in the same patients.

The null hypothesis was that no significant difference would exist in the clinical success of Class II composite restorations between pulpotomised and non-pulpotomised primary molars after 24 months.

Materials and methods

Ethical approval

This study was conducted in accordance with the principles of the Declaration of Helsinki. Ethical approval was obtained from the Ethics Committee of the Athens Dental Association (ref no: 1495). The trial was registered with Clinical Trials.gov (trial identifier: NCT07243496, 17-11-25). The parents of children who were eligible and invited to participate signed an informed consent agreement.

Study design

This was a prospective within-patient controlled clinical study. In the same patient, resin composite restorations were placed in Class II cavities of carious primary molars following pulpotomy, and in Class II cavities of carious primary molars that did not require pulpotomy. Randomisation was not feasible, because tooth allocation depended on clinical pulpal status. The study took place between September 2023 (first participant recruited) and April 2026 (last participant evaluated).

Sample size

Sample size estimation was based on McNemar's test for paired binary outcomes, appropriate for the within-patient study design (Machin et al. 2009). Using a two-sided alpha level of 0.05 and 80% power, a minimum sample size of 30 per group was considered sufficient to detect a difference in restoration success between pulpotomised and non-pulpotomised teeth. To allow for losses to follow-up during the 24-month observation period, the initial recruitment sample was increased to 40 children.

Inclusion criteria

- Healthy children 4–8 years old, ASA I.
- At least one carious primary molar requiring pulpotomy and Class II resin composite restoration.
- At least one carious primary molar requiring a Class II resin composite restoration without pulpotomy in the same patient.
- No clinical signs of pulpal necrosis (e.g., pathological mobility, abscess/ sinus tract) in teeth to be restored.
- Preoperative radiographs present.
- Signed parental informed consent.
- Patient attendance at follow-up appointments at 12 and 24 months.
- No natural exfoliation or extraction of the included teeth before the 24-month follow-up.

Data collection

Demographic and baseline clinical data were collected, including age, gender, and DMFT/dmft index.

Clinical procedure and evaluation

All restorations were performed by the same clinician (NNL). All restorations were placed in the same private

clinic. Due to the nature of the clinical procedure, operator blinding was not possible. Standardised isolation with rubber dam and local anaesthesia was applied in all cases. Class II resin composite restorations were placed after complete caries tissue removal, use of a sectional matrix system (Omni-Matrix, Ultradent®, Germany), etching of enamel and dentine with 37% phosphoric acid for 15 s, application of a fifth-generation bonding agent (Prime & Bond NT, Dentsply®, USA) and placement of composite resin (Filtek Universal, 3 M ESPE®, USA) in one increment. For polymerisation (20 s for bonding agent and 40 s for composite), the light curing unit Radii Plus from SDI®, Australia was used.

In teeth undergoing pulpotomy, after completion of the procedure and placement of NeoMTA from Nusmile®, USA, a liner of glass-ionomer cement (Vitrebond Plus, 3 M®, USA) was applied prior to the composite restoration using the same adhesive and restorative protocol.

Patients were recalled at 12 and 24 months for follow-up examinations. Restorations were evaluated using the modified U.S. Public Health Service (USPHS) criteria. The USPHS criteria are a standardised dental framework used to evaluate the clinical performance and longevity of restorations, such as composite fillings, typically rated as Alfa (ideal), Bravo (acceptable), or Charlie/Delta (unacceptable/reparation needed). They assess key parameters including marginal integrity, marginal discoloration, secondary caries, wear and surface texture (Gianordoli-Neto et al. 2016). Restoration success was defined as the absence of clinically unacceptable USPHS scores requiring replacement or repair during the follow-up period.

All evaluations were conducted by the same calibrated and blinded examiner (MA), distinct from the treating clinician, and unaware of whether the tooth had pulpotomy or not. Prior to the study, the examiner was calibrated in the use of the modified USPHS criteria through the evaluation of restorative cases not included in the study. Additionally, some random restorations were also assessed by the operating clinician to ensure agreement and no discrepancies were found.

Statistical analysis

Data were analysed using SPSS version 26.0 (SPSS Inc. Chicago, IL, USA). Descriptive statistics were calculated for demographic and clinical variables. Baseline characteristics between groups were compared using the Chi-square test. Cross-sectional comparisons of modified USPHS criteria between pulpotomised and non-pulpotomised teeth at 12 and 24 months were performed using the Chi-square test or Fisher's exact test where appropriate.

For longitudinal analysis, only teeth evaluated at both follow-up examinations were included. Changes in USPHS scores between the 12- and 24-month recalls within each group were analysed using the McNemar–Bowker test for paired categorical data. Statistical significance was set at $p < 0.05$.

Exploratory logistic regression analysis was additionally performed to evaluate the association between jaw location, molar type, and deterioration in marginal integrity at the 24 month evaluation.

Results

Trial sample characteristics

A total of 40 children (80 teeth) were initially recruited for the study. At the 12 month recall, 3 children were lost to follow-up, resulting in the evaluation of 37 children and 74 teeth. Baseline demographic and clinical characteristics were therefore analysed for these 37 children (Table 1). At the 24-month recall, 5 more children were lost to follow-up, resulting in a final sample of 32 children and 64 teeth. Amongst the 37 children attending the year 1 recall, 26 were boys (70.3%) and 11 were girls (29.7%) with a mean age of 5.6 ± 1.1 years and range from 4 to 8 years. The mean dmft at the time of treatment was 7.0 ± 2.1. The total number of first primary molars included was 53 (72%) and that of second primary molars was 21 (28%). The total number

Table 1 Baseline tooth-related characteristics of the evaluated teeth

Variable	With pulpotomy *N* (%)	Without pulpotomy *N* (%)	Total (*n*)	*P* value (Chi-square)
Jaw				0.18
Maxilla	18 (47.4%)	22 (61.1%)	40	
Mandible	20 (52.6%)	14 (38.9%)	34	
Tooth				0.39
First primary molar	29 (76.3%)	24 (66.7%)	53	
Second molar	9 (23.7%)	12 (33.3%)	21	
Total teeth	38	36	74	

of maxillary molars was 40 (54%) and that of mandibular molars was 34 (46%).

Baseline characteristics were comparable between the pulpotomy and non-pulpotomy groups, with no statistically significant differences observed in jaw location, or molar type ($p > 0.05$ for all variables).

Clinical outcome

The cross-sectional clinical performance of the restorations according to the modified USPHS criteria at the 12- and 24 month recalls is presented in Table 2. Overall, the majority of restorations in both groups remained clinically acceptable throughout the study period, with most restorations receiving Alfa scores for all evaluated criteria.

Marginal integrity was the parameter most frequently associated with deterioration over time and demonstrated the greatest differences between groups. At the 12-month recall, pulpotomised teeth showed significantly lower marginal integrity scores compared with non-pulpotomised teeth ($p = 0.003$), with a greater frequency of Bravo and Charlie scores. The difference between Bravo and Charlie was satisfactory adaptation with minor discrepancies that do not compromise the restoration's function or longevity (B) or noticeable discrepancies affecting marginal adaptation and potential for further issues (C). This difference remained statistically significant at 24 months ($p = 0.011$), indicating a progressive decline in marginal integrity in the pulpotomy group over time.

Marginal discoloration showed a tendency towards increased Bravo scores at 24 months in both groups, particularly in pulpotomised teeth; however, the differences between groups did not reach statistical significance at either recall period ($p > 0.05$). Similarly, surface texture and wear demonstrated predominantly Alfa scores in both groups, with only limited Bravo and occasional Charlie scores observed during follow-up. No statistically significant differences were identified between groups for these criteria at either the 12- or 24-month evaluations ($p > 0.05$). At the 12- and 24-month recall, no postoperative sensitivity was recorded in either group.

Recurrent caries lesion occurrence was limited. At 12 months, recurrent caries lesions were detected in only one tooth in the pulpotomy group and in none of the non-pulpotomised teeth. At 24 months, two teeth in the pulpotomy group demonstrated recurrent caries lesions, whilst no recurrent caries was observed in the non-pulpotomy group. The differences between groups were not statistically significant ($p > 0.05$).

Table 2 Cross-sectional clinical performance of Class II composite resin restorations according to modified USPHS criteria at 12- and 24-month follow-up evaluations

Criteria	12 months With pulpotomy no (%)	12 months Without pulpotomy no (%)	*P* value (12 m)	24 months With pulpotomy no (%)	24 months Without pulpotomy no (%)	*P* value (24 m)
Marginal integrity						
A	16 (43.2%)	30 (81.1%)	0.003	14 (43.8%)	25 (78.1%)	0.011
B	19 (51.4%)	7 (18.9%)		15 (46.9%)	7 (21.9%)	
C	2 (5.4%)	0 (0%)		3 (9.4%)	0 (0%)	
Marginal discoloration						
A	31 (83.8%)	36 (97.3%)	0.18	25 (78.1%)	29 (90.6%)	0.27
B	5 (13.5%)	1 (2.7%)		6 (18.8%)	3 (9.4%)	
C	1 (2.7%)	0 (0%)		1 (3.1%)	0 (0%)	
Surface texture						
A	32 (86.5%)	33 (89.2%)	0.62	28 (87.5%)	31 (96.9%)	0.35
B	4 (10.8%)	4 (10.8%)		3 (9.4%)	1 (3.1%)	
C	1 (2.7%)	0 (0%)		1 (3.1%)	0 (0%)	
Wear						
A	33 (89.2%)	35 (94.6%)	0.71	29 (90.6%)	31 (96.9%)	0.39
B	3 (8.1%)	2 (5.4%)		2 (6.3%)	1 (3.1%)	
C	1 (2.7%)	0 (0%)		1 (3.1%)	0 (0%)	
Postoperative sensitivity						
A	37 (100%)	37 (100%)	–	32 (100%)	32 (100%)	–
Recurrent caries						
A	36 (97.3%)	37 (100%)	0.31	30 (93.8%)	32 (100%)	0.15
C	1 (2.7%)	0 (0%)		2 (6.3%)	0 (0%)	

Longitudinal analysis of the matched sample, including only teeth evaluated at both follow-up periods (Table 3), demonstrated a statistically significant deterioration in marginal integrity over time in the pulpotomy group ($p = 0.041$). In contrast, no statistically significant longitudinal changes were identified in the non-pulpotomy group. Furthermore, no statistically significant longitudinal differences were observed for marginal discolouration, surface texture, wear, postoperative sensitivity or recurrent caries in either group ($p > 0.05$) (Table 3).

Exploratory multivariate logistic regression analysis demonstrated that jaw location (upper vs lower) and tooth type (first vs. second primary molar) were not significantly associated with deterioration of the restorations ($p > 0.05$). Only marginal integrity outcomes were included in the regression analysis (Table 4).

Table 4 Exploratory logistic regression analysis evaluating the association between jaw location, molar type, and marginal integrity deterioration at the 24-month follow-up evaluation

Variable	Odds ratio (OR)	95% CI	*P* value
Maxilla/mandible	1.81	0.63–5.20	0.269
First/second primary molar	0.52	0.15–1.78	0.296

Discussion

The present prospective 24-month study evaluated the clinical performance of Class II resin composite restorations in primary molars, comparing teeth treated with pulpotomy and teeth restored without pulpotomy. The main finding was that restorations placed in pulpotomised teeth demonstrated lower clinical performance based on USPHS criteria, particularly regarding marginal integrity. Importantly, however, no restoration failures requiring replacement were observed in either group during the follow-up period.

Teeth requiring pulpotomy are often more severely compromised at baseline, which may partly explain their less favourable restorative performance compared with teeth restored without pulp therapy (AAPD 2025). These teeth commonly present with extensive coronal destruction and reduced cusp support, weakening the remaining tooth-restoration complex under occlusal loading (Ghajari et al. 2020). In addition, larger Class II restorations may be more affected by polymerisation shrinkage stress, contributing to marginal gap formation and marginal breakdown over time (Soares et al. 2017). Together, these factors suggest that the inferior performance observed in the pulpotomy group may

Table 3 Longitudinal comparison of restorations evaluated at both the 12- and 24-month recalls according to modified USPHS criteria (matched sample)

Criteria	Group	12 months no (%)	24 months no (%)	*P* value (12 vs. 24 months)
Marginal integrity (MI)	With pulpotomy	A: 15 (46.9%) B: 15 (46.9%) C: 2 (6.3%)	A: 13 (40.6%) B: 16 (50.0%) C: 3 (9.4%)	0.041
	Without pulpotomy	A: 26 (81.3%) B: 6 (18.8%) C: 0 (0%)	A: 24 (75.0%) B: 8 (25.0%) C: 0 (0%)	0.317
Marginal discoloration (MD)	With pulpotomy	A: 27 (84.4%) B: 4 (12.5%) C: 1 (3.1%)	A: 24 (75.0%) B: 7 (21.9%) C: 1 (3.1%)	0.248
	Without pulpotomy	A: 31 (96.9%) B: 1 (3.1%) C: 0 (0%)	A: 29 (90.6%) B: 3 (9.4%) C: 0 (0%)	0.414
Surface texture (ST)	With pulpotomy	A: 28 (87.5%) B: 3 (9.4%) C: 1 (3.1%)	A: 27 (84.4%) B: 4 (12.5%) C: 1 (3.1%)	0.655
	Without pulpotomy	A: 28 (87.5%) B: 4 (12.5%) C: 0 (0%)	A: 28 (87.5%) B: 4 (12.5%) C: 0 (0%)	–
Wear (W)	With pulpotomy	A: 29 (90.6%) B: 2 (6.3%) C: 1 (3.1%)	A: 28 (87.5%) B: 3 (9.4%) C: 1 (3.1%)	0.564
	Without pulpotomy	A: 30 (93.8%) B: 2 (6.3%) C: 0 (0%)	A: 30 (93.8%) B: 2 (6.3%) C: 0 (0%)	–
Recurrent caries (RC)	With pulpotomy	Present: 1 (3.1%)	Present: 2 (6.3%)	0.564
	Without pulpotomy	Present: 0 (0%)	Present: 0 (0%)	–

reflect greater baseline structural compromise and restorative complexity rather than the pulpotomy procedure itself (Wu et al. 2021; AAPD 2025).

Previous clinical studies have demonstrated favourable performance of composite restorations in primary molars. For example, Gianordoli-Neto et al. (2016) reported high rates of Alfa scores across USPHS criteria over a 24-month period, indicating stable clinical performance. These findings are consistent with the present study, where the majority of restorations remained clinically acceptable at both follow-up appointments. Regarding restorations in primary teeth with previous endodontic treatment, a recent study found no statistically significant difference in success rates between resin composite restorations (86.7%) and PMCs (82.6%) after 1 year (Olegário et al. 2022).

However, when compared with other restorative approaches for Class II cavities in primary molars, important differences become evident. Resin-modified glass-ionomer cements (RMGICs) have been associated with inferior mechanical properties and higher failure rates, particularly in multisurface restorations, due to lower wear resistance and weaker adhesion (Duggal et al. 2022). In contrast, PMCs consistently demonstrate superior durability and lower failure rates, particularly in structurally compromised teeth, due to their full coronal coverage and ability to withstand occlusal forces (Innes et al. 2015; Wu et al. 2021).

The findings of the present study are in agreement with the available recent literature showing that resin composite restorations in pulpotomised primary molars may demonstrate slightly inferior clinical performance compared with restorations placed in less structurally compromised teeth (Wu et al. 2021; Biedma-Perea et al. 2025). In the present study, marginal integrity was the only parameter showing statistically significant differences between groups and longitudinal deterioration over time. Nevertheless, the majority of restorations in both groups remained clinically acceptable after 24 months, whilst recurrent caries and postoperative sensitivity were minimal. Restorations which scored Charlie were kept under review, as clinically they did not require replacement. These findings suggest that although pulpotomised teeth may be more susceptible to marginal degradation due to increased cavity size, reduced residual tooth structure, and increased polymerisation stress, adhesive composite restorations may still provide satisfactory outcomes when appropriate case selection and optimal clinical protocols are followed (Soares et al. 2017; Wu et al. 2021; AAPD 2025). Importantly, despite the statistical differences in marginal integrity, restoration survival remained high in both groups throughout the 24-month follow-up period.

Overall, the findings of the present study suggest that resin composite restorations may provide acceptable clinical outcomes in selected pulpotomised primary molars when appropriate adhesive protocols and isolation are achieved. Nevertheless, restoration performance remains influenced by cavity size, remaining tooth structure, and functional loading. Although PMCs remain the most predictable restorative option for extensively compromised primary molars, resin composite restorations may represent a conservative and aesthetic alternative in carefully selected cases.

Strengths and limitations

The strengths of the present study include its prospective within-patient design, which minimised inter-individual variability, the standardised clinical protocol performed by a single operator, and the use of blinded outcome assessment. In addition, the inclusion of both cross-sectional and longitudinal analyses provided a more comprehensive evaluation of restoration performance over time.

The findings of the present study should, however, be interpreted in light of several limitations. Although a within-patient design was used to reduce inter-individual variability, the absence of randomisation introduces potential selection bias, as teeth requiring pulpotomy were inherently more severely affected at baseline, due to the additional preparation required for the pulpotomy procedure. Additionally, the evaluated teeth did not always have anatomically matched contralateral counterparts. This difference in lesion severity and remaining tooth structure which was not recorded at baseline may have influenced the comparative outcomes.

Finally, the relatively small sample size and loss to follow-up over the 24-month period may limit the statistical power and generalisability of the findings. Although the follow-up period is clinically relevant, it may not fully capture the long-term survival of restorations in primary molars until exfoliation. Furthermore, all restorations were performed by a single clinician under optimal conditions, including rubber dam isolation, which enhances internal validity but may limit applicability to general clinical practice.

Clinical implications

Resin composite restorations may be considered a viable option for Class II cavities in primary molars, including pulpotomised teeth, when adequate tooth structure remains and optimal isolation can be achieved. However, in cases of extensive coronal destruction, full-coverage restorations such as PMCs should be preferred to maximise longevity and minimise failure risk. Careful case selection remains critical for clinical success.

Conclusions

Within the limitations of this prospective 24-month study, Class II resin composite restorations in primary molars showed acceptable performance in both groups, although pulpotomised teeth demonstrated reduced marginal integrity after 24 months. In extensively compromised primary molars, full-coverage restorations remain the most predictable option, but resin composite may be used as an aesthetic alternative in carefully selected cases.

Author contributions Nikos N. Lygidakis (NNL) conceived the idea. NNL did the restorations and Myrto Alevra (MA) did the follow-up and the blinded clinical examination of the restorations at 12 and 24 months. NNL and MA did the statistics and drafted the paper. Nick A. Lygidakis (NAL) revised the paper. The final draft was approved by all authors.

Data availability No datasets were generated or analysed during the current study.

Declarations

Conflict of interest The authors declare no competing interests.

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