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Clinical outcomes of direct resin-composite restorations in primary maxillary incisors in patients with early childhood caries: a prospective non-controlled cohort study

Fangfei Zhang¹, Guannan Liu¹, Yu An¹ and Yuhong Liang^{2*}

Abstract

Objectives Maxillary primary anterior teeth are primarily affected by early childhood caries (ECC), and treatments are challenging. The aim of this study was to evaluate the clinical outcomes and risk factors for chairside direct composite restorations of maxillary primary incisor caries in patients with ECC.

Materials and methods A total of 160 maxillary incisors from 54 children aged 23–47 months who were diagnosed with caries and received direct-bonded composite restoration treatments according to the standard protocol were included. At 1 year of follow-up, the restorations were evaluated using the modified United States Public Health Service (USPHS) criteria. A restoration was defined as successful when Alpha or Bravo scores were obtained for all parameters. The presence of secondary caries, fracture or restoration loss, and pulpal or periapical pathosis were recorded as failures.

Results Forty-six patients completed the 1-year follow-up visit, and 133 restorations were analysed, with a recall rate of 83.1% for restorations and 85.2% for patients. Ninety-two restorations (69.2%) were judged as successful. Secondary caries was found in 27 teeth (20.3%), fracture or restoration loss in 35 teeth (26.3%), and pulpal or periapical pathosis in 5 teeth (3.8%). Logistic regression analysis revealed that the number of carious surfaces was a risk factor for outcomes (OR 3.730, 95% CI 1.494 ~ 9.313, P value 0.005).

Conclusions Direct resin-composite could restore primary maxillary incisors in children with one to two caries-involved surfaces.

Keywords Early childhood caries, Direct resin-composite restoration, Maxillary primary incisors

*Correspondence: Yuhong Liang leungyuhong@sina.com ¹Department of Stomatology, Peking University International Hospital, No. 1 Shengmingyuan Road Zhongguancun Life Science Park, Beijing 102206, PR China ²Department of Emergency, Peking University School and Hospital of Stomatology & National Center for Stomatology & National Clinical Research Center for Oral Diseases & National Engineering Research Center of Oral Biomaterials, Digital Medical Devices & Beijing Key Laboratory of Digital Stomatology & NHC Key Laboratory of Digital Stomatology & NMPA Key Laboratory for Dental Materials, No. 22 Zhongguancun South Avenue, Haidian District, Beijing 100081, PR China



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Introduction

Early childhood caries (ECC), one of the most prevalent diseases affecting infants and preschoolers worldwide, is defined as the presence of decayed, missing or filled teeth in the primary dentition of children younger than 6 years [1, 2]. In the Global Burden of Disease Study in 2017, 7.8% of the global population was reported to have untreated primary tooth caries [3]. The 4th National Oral Health Survey in Mainland China showed that the prevalence of early childhood caries in 3- and 4-year-old children was 50.8% and 63.6%, respectively, but only 1.5% and 2.9% of those with caries received treatments in practice [4].

ECC type II is characterized by labiolingual carious lesions affecting maxillary incisors, with or without molar caries depending on the age of the child and stage of the disease, and unaffected mandibular incisors [5]. Due to the small size of the clinical crown, close proximity of the pulp to the tooth surface, relatively thin enamel and lack of surface area for bonding, the sensitivity of the technique in placing aesthetic restorations for primary incisors is high [6]. Children with ECC who develop dental caries in the primary incisors are generally very young and have a greater propensity for developing secondary caries [7]. Their negative behaviours could influence the outcomes of treatment [8]. Therefore, maxillary incisor restorations are especially challenging, and the outcomes are uncertain.

There is a lack of supporting clinical data on the outcomes of providing resin-composite restorations in primary maxillary incisors for young children. In Amend's evidenced-based review published in 2022, only 2 of the 29 randomized controlled clinical trials were performed on primary incisors, in which the clinical effectiveness of restorative materials for the restoration of carious primary teeth with vital pulp was evaluated [9]. In 8 previously published clinical studies on directbonded resin-composite restorations of anterior primary teeth for children with ECC, half of the treatments were administered under general anaesthesia to improve the conditions, and the success rate ranged from 71-91.3% [10–17]. The reported success rates were 72% after 1 year and over 85% after 2 years in 2 chairside clinical trials on anterior teeth with moderate-to-minimal caries [10, 11]. Due to the sample characteristics of the studies, these results may only partially reflect the outcomes of restorations in reality.

The aim of this study was to evaluate the clinical outcomes and risk factors for chairside direct composite restorations of maxillary primary incisor caries in patients with ECC. The hypothesis raised here is that the number of risk factors influences the clinical outcomes of direct composite resin restorations placed on upper primary incisors diagnosed with ECC type II over a 12-month follow-up.

Materials and methods

Patient inclusion

This prospective non-controlled cohort study protocol was approved by the ethics board of Peking University International Hospital, Beijing, China (Approval No. 2019-038 (BMR)). This study was designed and carried out as the Flow diagram (Fig. 1). Patients under 4 years old who were diagnosed with ECC (Wyne classification ECC II) [5] and who received direct-bonded composite restoration treatments for carious maxillary incisors in the Department of Stomatology at Peking University International Hospital, Beijing, China, between April 1, 2019, and December 31, 2019, were enrolled in the study.

The inclusion criteria were as follows:

- Symptomless and vital maxillary incisors diagnosed as caries (codes 4–6) according to the International Caries Detection and Assessment System (ICDAS) [18].
- Patients who had behavioural ratings of 0–1 according to Venham's cooperative behaviour rating scale (Supplementary Table 1) during treatment [19].
- 3. Presence of the opposite tooth.

The exclusion criteria were as follows:

- 1. Patients who had behavioural ratings of 2–5 according to Venham's cooperative behaviour rating scale during treatment and needed general anaesthesia, sedation or protective stabilization.
- 2. Patients with systemic diseases such as heart disease or cancer.
- 3. Patients with anterior crossbites or bruxism.
- 4. Teeth had been subjected to trauma.

In total, the cohort consisted of 160 maxillary incisors from 54 children. Information, including demographic information, clinical parameters, and dental treatment information, was recorded.

Restoration procedures

All the treatments in this study were performed by three dentists (FFZ, GNL and YA) who had at least 5 years of experience in paediatric oral care, and all the children received direct composite restoration treatments according to the standard protocol.

Local anaesthesia was applied when necessary. Isolation of operative field was performed by rubber dam or cotton roll. Rotary burs were used to remove caries from outer layer and lateral walls of the cavity. The soft carious dentine close to the pulp was removed by spoon



Fig. 1 Flow diagram of the trial

excavators and Carisolv III system ° (ADV.dental, Wuhan, China). A short bevel was prepared on the cavosurface margin. The two-step self-etch adhesive Clearfil SE Bond primer (Kuraray Noritake Dental Inc, Kurashiki, Japan) was applied to the tooth with a brush in a gentle back and forth motion for 20 s and gently dried with compressed air from an air syringe. A thin layer of Clearfil SE Bond (Kuraray Noritake Dental Inc, Kurashiki, Japan) was applied over the primed preparation with a brush and distributed evenly with mild air flow and was light cured for 10s with Coltene S.P.E.C. 3 LED curing light (Coltene/ Whaledent Inc., Cuyahoga Falls, OH, USA). The light output was at least 1600 mW/cm2 in all applications. Filtek Z350XT Flowable Restorative in shade A3 (3 M ESPE, St. Paul, MN, USA) was used as liner base and cured for 20s. A small portion of composite resin, Filtek Z250 Universal Restorative composite resin in shade A1 (3 M ESPE, St. Paul, MN, USA), was placed on the cavity and cured for 20s without increment technique due to the small size of primary teeth, which was less than 2 mm. For approximal lesions, a celluloid matrix (Polyester Matrix Band, Microdont, SP, Brazil) and a wedge (Hawe Sycamore Interdental Wedge, Kerr Dental, Bioggio, Switzerland) were placed. No strip crowns or other crown forms were used. Excess material was removed using finishing burs after checking contact points with articulation paper.

After treatment, all the children received topical fluoride treatment with 50 mg/ml Duraphat Dental Suspension (Colgate-Palmolive (UK.) Limited, Waltrop, Germany). Individual oral health instructions were provided to the children and their guardians.

Follow-up examination

One year after treatment, the included patients were contacted by telephone to encourage them to attend the follow-up appointment.

The follow-up clinical examination was carried out by two trained examiners (FFZ and GNL) according to modified United States Public Health Service (USPHS) criteria in terms of anatomic form, marginal adaptation, marginal discolouration, secondary caries, colour match, postoperative sensitivity and retention (Table 1) [20]. A restoration was defined as successful when an Alpha or Bravo score was obtained for all the parameters. Furthermore, the visible plaque index [21] was used to evaluate routine plaque control. For the calculation of this index, the number of dental surfaces was divided by the surfaces with a visible plaque. For the analysis, the values of the index were dichotomized. A satisfactory biofilm control was considered when the visible plaque index was less

Criteria	Alpha	Bravo	Charlie
Anatomic form	The restoration is continuous with existing anatomic form.	The continuity of restoration with teeth partially degraded, but clinically acceptable.	The continuity of restoration with teeth completely deteriorated, need to be replaced.
Marginal adaptation	There is no visible evidence of a crevice along the margin into which the explorer will penetrate.	There is visible evidence of a crevice along the margin into which the explorer will penetrate or catch.	The explorer penetrates the crevice, and dentin or base is exposed.
Marginal discolouration	There is no discolouration anywhere on the margin between the restoration and the tooth structure.	Discolouration is present but has not penetrated along the margin in a pulpal direction.	Discolouration has penetrated along the margin in a pulpal direction.
Secondary caries	No evidence of secondary caries.	_	Evidence of secondary caries.
Colour match	The restoration matches the adjacent tooth structure in colour and translucency.	The mismatch in colour and translucency is within the acceptable range.	The mismatch in colour and translu- cency is outside the acceptable range.
Postoperative sensitivity	No postoperative sensitivity at any stage of the study	Slight sensitivity at any stage of the study.	Severe sensitivity at any stage of the study.
Retention	No loss of restorative material.	_	Fracture and/or loss of restorative material.

Table 1 Modified united States public health service (USPHS) criteria adapted from Ryge's criteria [20]

Alpha: ideal clinical outcome; Bravo: acceptable clinical outcome; Charlie: unacceptable clinical outcome

 Table 2
 Outcomes of resin restorations based on the modified USPHS criteria

Criteria	Alpha	Bravo	Charlie
Anatomic form	92 (69.2%)	12 (9.0%)	29 (21.8%)
Marginal adaptation	90 (67.7%)	12 (9.0%)	31 (23.3%)
Marginal discolouration	87 (65.4%)	15 (11.3%)	31(23.3%)
Secondary caries	106 (79.7%)	_	27 (20.3%)
Colour match	97 (72.9%)	11 (8.3%)	25 (18.8%)
Postoperative sensitivity	128 (96.2%)	0	5 (3.8%)
Retention	98 (73.7%)	_	35 (26.3%)

than 20% [15]. Intra- and interexaminer agreement was determined. When any disagreements occurred during the evaluation, the final decision was made by obtaining a consensus of both examiners after discussion.

Statistical analysis

The data, including patient demographics, tooth status and clinical outcomes, were collected from patient records, encoded into Microsoft Excel and analysed by IBM-SPSS version 26.0 (IBM Corp., Armonk, NY). The kappa test was performed to evaluate intra- and interexaminer agreement. Risk factors related to the success rate of the restorations were identified via logistic regression analysis. The level of significance was set at $\alpha = 0.05$.

Results

Follow-up information

Forty-six patients aged 23–47 months with 133 resin restorations completed the 1-year follow-up visit after treatment. The recall rate was 83.2% (133/160) for restorations and 85.2% (46/54) for patients. The reasons for dropout were that the patients were unable to be contacted or refused to participate.

Among the 46 patients, 26 were male and 20 were female. The mean age was 37 months at the first visit.

At baseline, the decayed, missing and filled teeth (dmft) index and decayed, missing and filled surface (dmfs) index scores were $8.7(\pm 3.0)$ and $15.4(\pm 7.5)$, respectively; these scores increased to $10.3(\pm 3.1)$ and $19.0(\pm 7.9)$, respectively, at the 1-year follow-up.

Outcome assessment and prognostic factor analysis

The inter-examiner kappa value (between FFZ and GNL) for determining the outcome of restorations was 0.875. The intra-examiner kappa values for two examiners at a 1-week interval were 0.905 (FFZ) and 0.840 (GNL), respectively. The quality of the restorations is presented in Table 2. Among the 133 restorations, 92 were judged as successful, and the success rate was 69.2% (Fig. 2).

Among the 41 restorations considered to have failed, secondary caries were found in 27 teeth (20.3%), fracture or loss of restoration was found in 35 teeth (26.3%), and pulpal or periapical pathosis was found in 5 teeth (3.8%) (Fig. 3). Thirty-six restorations needed replacement, but only 28 restorations were retreated, and the other 8 restorations were left for observation because the parents refused retreatment. Of the 5 teeth with pulpal or periapical pathosis, root canal treatments were performed for two, and the other three were extracted.



Fig. 2 Three incisors (left and right central incisors and left lateral incisor) of a 3-year-old girl were determined to have caries, left and right central incisor were scored as 5 by ICDAS with 4 surfaces involved and left lateral incisor was scored as 4 by ICDAS with 2 surfaces involved (**a**). Direct-bonded composite restoration treatments were performed (**b**-**c**). At 1 year of follow-up, the three restorations were judged to be successful (**d**)



Fig. 3 The restoration in the left upper central incisor of a 3-year-old boy was judged to have failed at the 1-year follow-up because of dislodgment of the restoration (**a**), and the restoration was replaced by a resin composite (**b**). The left upper central incisor were scored as 5 by ICDAS with 4 surfaces involved at first visit

 Table 3
 Logistic regression analysis of the potential risk factors influencing the success rate of restorations

Factors		Number of teeth	Success rate(%)	Adjusted odds ratio	95% confidence interval		P value
					Lower	Upper	
Sex	Male	77	66.2				
	Female	56	73.2	0.657	0.276	1.564	0.342
Teeth location	Central incisor	69	69.6				
	Lateral incisor	64	68.6	1.367	0.584	3.201	0.472
Caries-involved surfaces	1–2	92	78.3				
	3–4	41	48.8	3.730	1.494	9.313	0.005*
Venham's behaviour rating scale	0	80	75.0				
	1	53	60.8	1.200	0.514	2.802	0.673
Isolation type	Cotton	69	60.9				
	Rubber dam	64	76.8	0.510	0.227	1.150	0.104
Visible plaque index(follow-up)	≤20%	83	77.1				
	>20%	50	56.0	1.786	0.743	4.295	0.195

 * Bold font highlights statistical significance measured by the backward Wald test

Binary logistic regression analysis revealed that teeth with 3 or more caries surfaces involved (OR 3.730, 95% CI 1.494 ~ 9.313, P value 0.005) was a risk factor for outcome (Table 3). The failure risk in teeth with 3 or more surfaces involved was 3.7 times greater than that in teeth with 1-2 surfaces involved.

Discussion

Maxillary anterior caries develops soon after the eruption of teeth and progress rapidly in children with ECC [22]. Restoration of carious primary maxillary incisors is essential for function, speech, aesthetics and the maintenance of space for the eruption of permanent teeth [23]. Parents were generally aware of the aesthetic defects in their children's teeth, and 87% of parents advocated for dental treatment to save a primary tooth even if the chance for success was only 50% [24]. The demand for aesthetic restoration for young children is high, but patient cooperation is questionable. It is a formidable challenge for paediatric dentists to restore primary maxillary incisors, especially for children under 4 years of age.

Various restorative materials are available for the restoration of primary maxillary incisors, including intracoronal restorations, such as resin composites, glass ionomer cements (GICs), resin-modified glass ionomers (RMGIs) or polyacid-modified resins, and full-coronal restorations, such as resin composite strip crowns, preveneered stainless steel crowns and prefabricated primary zirconia crowns. In this study, a resin composite was used because of its strength, wear resistance, aesthetics, and colour-matching capabilities, and this minimally invasive treatment is acceptable to clinicians and patients in the clinic [8]. Silver diamine fluoride (SDF) at 38% is suggested to be effective in arresting ECC, but it stains caries black which is not esthetically pleasing [25]. Atraumatic restorative treatment (ART) with high-viscosity GIC has been advocated in treating primary teeth for young and uncooperative children [23]. However, the success rate of ART in restoring anterior primary teeth is unfavourable. Two-thirds of restorations in anterior teeth failed within the first year after ART placement [26]. In recent years, prefabricated strip crowns and zirconia crowns have also been used for better aesthetics, but the chairside time consumption of full coronal restoration treatment puts pressure on clinicians when treating young children [8]. With the development of digital techniques, it's prospective to restore these teeth using chairside manufactured crowns.

In the present study, all the treatments were conducted in the clinical setting, and patient management, which included a variety of nonpharmaceutical behaviour guidance techniques such as communicative guidance, the tell-show-do technique, voice control, positive reinforcement, and audiovisual distraction, was performed to help children achieve good cooperation. To avoid pain and dental fear, combination of gentle removal caries using burs and chemomechanical methods were used. When the aforementioned behaviour guidance techniques were ineffective in practical, other management methods including general anaesthesia, sedation or protective stabilization may be considered.

A modified version of the USPHS criteria was applied in the present study, and it is the most commonly used criterion to evaluate dental restorations. A restoration was defined as successful when an Alpha or Bravo score was obtained for all parameters, and the success rate was 69.2%. This result was comparable to those of two previous studies, which reported success rates of 71% and 72.3% after 16.5 months and 12 months of follow-up, respectively, and these studies were conducted under general anaesthesia [12, 13]. Moreover, in two retrospective studies in which treatments were conducted chairside, a relatively low survival rate of 44.7% was observed in 0–3-year-old children after a mean follow-up time of 24 months in one study, and in the other study, after 1.7 years of follow-up in older children with a mean age of 6.6 years, a higher success rate of 79.4% was observed [15, 17].

Resin composite restorations are a sensitive technique, and the success rate is associated with factors such as cavity size and type, tooth location in the dental arch, operator experience, and patient characteristics [27]. The adequacy of sample size for multivariate logistic regression analysis is to have at least 10-20 events per predictor [28]. Six factors were selected as covariates, and a total of 133 restorations were included in the analysis, allowing for 21 cases for each predictor in the model. Logistic regression analysis revealed that the number of involved carious surfaces influenced the success rate of restorations. Among the 41 failed restorations, 21 (51%) involved 3 or more affected surfaces, 76.2% of which had fractures or restoration loss. We also found that the success rate of restoration for teeth with 3 or more affected surfaces was 48.8%, which was 29.5% lower than that for teeth with 1-2 affected surfaces. Similar results were found in previous studies [15, 17]. It indicated alternative treatment options should be considered to achieve a more enduring clinical outcome when three or more surfaces are affected.

A combination of flowable and packable composites were used in the study. Similar overall clinical performance was reported for different types of composites in the restoration of carious primary molars [29, 30]. However, there was a lack of relevant studies concerning primary anterior teeth. To minimize bias introduced by different operators, only paediatric dentists with at least 5 years of experience were included and the three participating dentists were trained before the study was conducted. The success rates of three different dentists were 69.3%, 64.1% and 78.9% separately. The chi-square test showed there were no statistically significant differences among the three groups (P=0.516).

In our study, 30.8% of restorations were considered as failure, mainly due to fracture or restoration loss, followed by secondary caries. Nevertheless, 87.8% of the failed restorations could be repaired. At the 1-year follow-up, only 5 teeth (3.8%) had pulpal or periapical pathosis. This finding was consistent with previously reported percentages of composite strip crowns, which indicated pulp health rates ranging from 91–97% [31, 32]. It has been suggested that the ultimate goal of restoring severely decayed anterior primary teeth is to allow patients to retain these teeth and allow for natural exfoliation without any pulpal complications [32]. The results of this study indicated that resin composites were effective at restoring caries lesions and protecting pulp health in primary incisors.

The management of ECC is multifactorial, and highquality restoration is only one of the contributing factors [2]. Caries recurrence rates ranging from 18.8 to 79% after 6 to 24 months were reported in previous literature, even if comprehensive treatments under general anesthesia were adopted [7, 12, 33]. Regular postoperative follow-up visits are important for children with ECC. According to the recommendations of the American Academy of Pediatric Dentistry, children with a high caries risk are encouraged to complete follow-up every three months and receive preventive care [34]. However, during the COVID-19 pandemic, good compliance was difficult to achieve. Nevertheless, the study reflected the real clinical situation and provided valuable data about the outcomes and potential risk factors for the failure of composite restorations for primary incisors in children with ECC.

It should be careful to interpret the result because this study only evaluated the outcomes of direct composite resin restorations on teeth diagnosed with ECC type II over a 12-month follow-up without a control group, and the performance of the other options of restorations need further exploration.

Conclusion

Composite resin restoration for primary incisors in young children is a challenging and sensitive technique. Direct resin-composite could restore primary maxillary incisors in children with one to two caries-involved surfaces.

Supplementary Information

The online version contains supplementary material available at https://doi.or g/10.1186/s12903-025-05814-9.

Supplementary Material 1

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Author contributions

YHL and FFZ created the conception and design of the study. FFZ, GNL and YA collected the data. FFZ and YHL wrote the main manuscript text. All authors reviewed the manuscript.

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Data availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Human Ethics and Consent to Participate declarations

The study was approved by the ethics board of Peking University International Hospital, Beijing, China (Approval No. 2019-038 (BMR)). The study procedures

were conducted in accordance with the principles outlined in the Declaration of Helsinki and complied with the laws and regulations covering Good Clinical Practice (GCP) in China. Informed consent was provided by the parents/ guardians of the participants. By signing the consent form, the participants consented to the processing of their personal data without revealing their identity information.

Competing interests

The authors declare no competing interests.

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