ABSTRACT:
Objective: To investigate the occurrence of caries associated with restorations in primary molars.
Methods: Resin-modified glass ionomer cement (n=50) and compomer (n=50) restorations of primary molars were made in 100 children. The restorations were clinically evaluated on the 3rd, 6th, 12th and 18th month with the FDI criteria.
Results: On the 3rd month recall, all restorations showed excellent clinical assessment scores for all FDI criteria. In regard to secondary caries, on the 6th month, clinically unacceptable was only one restoration. In the 12th month, 19.00% of the restorations were diagnosed with caries adjacent to the restoration. The relative share of secondary caries lesions assessed in restorations from glass ionomer cement (27.27%) was higher than that from compomer material (14.28%), as well as the restorations on the occlusal surface (38.46%), compared to those on the proximal surfaces (7.40%). Caries associated with restorations was diagnosed more frequently in relation to the caries lesions assessed as active at the first visit (29.62%) compared to the inactive lesions (7.69%). At the 18th month recall, the relative share of restorations diagnosed with secondary caries was lower (8.00%).
Conclusion: The type of restorative material, type of affected surface and the activity of the carious lesion are factors that may influence the occurrence of caries associated with restorations in primary molars. Our study showed that a critical moment for the clinical condition of the followed restorations is the 12th month of the treatment.

Keywords: caries associated with restorations, compomer materials, glass-ionomer cement, primary molars,

INTRODUCTION:
The main reason for the failure of dental caries treatment, both in primary and permanent teeth, is the appearance and progression of caries associated with an existing restoration [1-5]. Secondary caries is the cause of replacement of restorations in nearly 60% -70% of cases, regardless of the type of restorative material [2,15]. Other reasons for replacement of restorations are wear of the material, fracture or defect of the tooth or filling, complications from the pulp, poor aesthetics, etc. Regardless of the type of restorative material, the durability of restorations in primary and permanent children’s teeth is lower than in adults [10]. The risk factors for the occurrence of caries associated with restorations are identical to those for primary caries, but since these lesions can occur only secondarily, in the presence of restoration, a number of other factors are discussed in the literature - marginal integrity of the restoration [11-14]; type of restorative material [2,15]; dental practitioner’s experience [3]; type of tooth [16]; the position of the tooth in the tooth arch [17]; the shape and size of the restoration [16,18]; number of surfaces affected [19,20]; patient’s age [20]. The purpose of this study was to investigate the quality of dental restorations in primary teeth and especially the occurrence of caries associated with different types of restorative materials for an observation period of 18 months.

METHODS:
The study included a total of 100 randomly selected children aged 2 to 7 years, referred for dental treatment to the Department of Pediatric Dentistry, Faculty of Dental Medicine, Medical University of Plovdiv, Bulgaria. Selection criteria included cooperative children in good general health and with a presence of at least one affected from caries occlusal or proximal surface of a primary molar at diagnostic threshold D3 (cavitated or not cavitated dentinal caries). Children were included in the study after receiving informed consent from a parent. The examinations and treatment procedures were conducted in full accordance with ethical principles. All materials and devices used are certified for clinical use.

A detailed history, dental and oral hygiene status was filled in for each patient. A short questionnaire on the oral hygiene and nutritional habits of the participants was also included. Based on the data from the history of the patient and the clinical examination, the individual risk of oral diseases was determined. An individual program for prevention and individual treatment plan was made in accordance with the Consensus for the treatment of caries of primary teeth, adopted by the National Association of Pediatric Dentists in Bulgaria [21]. Signs of observation for each patient were: criteria for determining the risk of caries (general condition, total caries experience, level of oral hygiene, salivary factors, carbohydrate intake, fluoride prevention, social sta-
The primary molars included in the study were treated with conventional means and restored as follows: 50 with glass ionomer cement (RIVA SELF CURE - SDI Limited, Australia) and 50 with compomer material (Freedom - SDI Limited, Australia). The choice of restorative material for each patient was made on the basis of the individual oral risk, features of the caries lesion, behavior of the patient, control of saliva. Only one affected from caries primary molar per patient was included in the study. All restorations were performed by one author.

Control clinical examinations were performed on the 3rd, 6th, 12th and 18th month, with periodic control of the individual caries risk, monitoring of the individual preventive program and clinical assessment of the condition of the observed restorations. The assessment criteria include:

- biological properties (postoperative sensitivity and secondary caries),
- functional properties (marginal adaptation and fractures of restoration) and
- esthetic properties (marginal staining).

Restorations which needed replacement due to unacceptable clinical evaluation on the recalls were excluded from the study. Sealed, polished and repaired restorations continued in the follow-up. With the limits of this publication, only the results for the biological properties (secondary caries) of the followed restorations will be presented.

**Statistical analyses**

The data obtained were subjected to a statistical analysis using the statistical software package SPSS 17. The scores of FDI criteria were compared among each evaluation period in relation to the type of restorative material, type of surface and activity of the primary lesion. Descriptive statistics, the $\pm 2$ test of independence, mean $\pm$ standard deviation (SD), frequency and percentages were used to describe the numerical and categorical measurements. A value of $p<0.05$ was considered statistically significant.

**RESULTS:**

The study group included 47 (47%) boys and 53 (53%) girls with a mean age of 4.85 ± 0.36 years. The dental status of the participants showed that the number of decayed primary teeth (d) varies between 1 and 18 teeth ($d=4.70\pm3.023$). The number of restored primary teeth (f) was between 0 and 7 teeth ($f=1.63\pm2.028$). No significant difference was found between the gender and the number of carious teeth ($\chi^2=10.106, p=0.521$), as well as the gender and the number of restored teeth ($\chi^2=12.236, p=0.093$).

The quality of oral hygiene, assessed by the simplified Greene-Vermillion index (OHI-S), showed a statistically significantly higher relative share of children with good oral hygiene (OHI-S: 0-1) - 89.00% of the surveyed. Unsatisfactory oral hygiene (OHI – S: 1.1-2) showed 11.00% of the surveyed ($\chi^2=60.840, p = 0.000$).

Assessment of the individual risk of dental caries showed that 98.00% of the observed children were at high risk mainly due to frequent consumption of carbohydrate foods and drinks and a high level of total caries experience. At low risk were only 2.00% of the participants.

The evaluation of the activity of initial carious lesions showed with no statistically significant difference that most of them (58.00%) were assessed as active ($\chi^2=2.560, p=0.110$).

On the 3-month recall, all restored primary molars had an excellent clinical assessment according to all FDI criteria. On the 6-month follow-up, most of the restorations (99.00%) were evaluated as “clinically excellent” (with codes 1 and 2). Only one restoration, assessed with code 4, was clinically unacceptable for this indicator.

On the 12th month recall, 7.00% of the restorations were excluded from the study due to the appearance of clinically unacceptable pathology and were fully replaced. With no signs of “secondary caries”, are 74.00% of the restorations. In 6.00% of the restorations, small marginal areas with a change in the transparency of the enamel (score 2) were found, which did not require operative treatment. The Presence of areas with demineralization in the enamel without the involvement of dentin (code 3) were found in 6.00% of the restored teeth, and 7.00% were evaluated with a code 4. There were no restorations assessed with code 5 on the 12th month of the observation. The relative share of caries associated with restoration at the 12th-month recall was 19.00%.

On the 18th-month recall, the share of restorations in primary molars, excluded from observation due to the appearance of clinically unacceptable pathology according to FDI criteria, was higher (27.00%). Most of the restored teeth showed no signs of caries adjacent to restoration (65.00%). Code 2 was evaluated at 1.00%, with code 3 - 2.00% of the restorations, and with code 4 - 5.00%. There are no restorations assessed with code 5. The relative share of caries associated with restorations at the 18th-month recall was 8.00%.

In relation to the type of restorative material, at the 6th month of the observation, there was no statistically significant difference in the prevalence of caries adjacent to glass ionomer restorations and those from compomer material. The relative share of teeth that developed pathology according to this criteria was low (8.69%) for both types of restorative materials ($\chi^2=0.465$). Caries associated with restorations was found significantly more frequent on the 12th-month recall in glass ionomer restorations (27.27%), compared to the relative share of secondary caries in teeth restored with compomer material (14.37%), ($\chi^2=0.014$).

On the 18th month recall, although without a significant difference, secondary caries was diagnosed more often in primary molars restored with glass ionomer (16.85%) than the restorations from compomer material (5.41%), ($p = 0.310$).

At the 6th month recall, the obtained results showed with significant difference in more frequent occurrence of secondary caries in relation to restorations on the occlusal surface compared to those on the proximal surface ($p = 0.019$). As shown on Graph. 1, the frequency of secondary caries at the 12th - month recall in relation to the type of surface was higher adjacent to occlusal restorations and significantly lower in the proximal restorations ($p=0.000$).
Graph. 1. Secondary caries scores at the 12th month recall in relation to the type of surface

Graph. 2 demonstrates the distribution of secondary caries scores at the 18th month recall in relation to the type of surface, were the relative share of carious lesions adjacent to restorations on the proximal surface is higher compared to that on the occlusal restorations with no statistically significant difference, ($p=0.254$).

Graph. 2. Secondary caries scores at 18th month recall in relation to the surface type

The activity of the primary lesion was also found important in relation to the occurrence of caries associated with restorations in primary molars. Our results showed a significantly higher incidence of secondary caries after treatment of carious lesions, assessed as “active” at the initial examination. The difference between active and inactive lesions was found significant both on the 12th ($p=0.032$) and on the 18th month recall ($p=0.003$). Graph 3 and Graph 4 present the relative share of secondary caries scores in relation to lesion activity in the 12th and 18th month, respectively.
DISCUSSION:
The data in the literature on the prevalence of caries associated with restorations in primary molars vary widely, depending on the type of restorative material, the age of the child, the type of tooth and tooth surface, the total caries experience, the cavity preparation and etc. The results obtained by us showed a relatively high share of caries associated with restorations in primary molars, especially in the 12th month of the observation. The pathology was more frequent in relation to glass ionomer restorations, occlusal restorations and in caries lesions assessed as active before the treatment. Our study showed that the activity of the primary caries lesion and the type of the affected tooth surface are relevant to the occurrence of a new pathology adjacent to restorations.

In a study of the incidence of dental caries in children aged 3-4 years, Bjarnason S et al. found secondary carious lesions in 38% of restored teeth [23]. Metz, I et al. followed composite restorations of primary teeth for a period of 8 years [24]. In the first 2 years, 72.6% were diagnosed with secondary carious lesions. According to the authors, the most common cause of failure in the treatment of dental caries in children is the appearance of a secondary carious lesion.

In the literature, there is no difference in the preventive effect of the glass ionomer restorations in relation to secondary caries compared to other restorative materials [25]. Bektas Donmez S et al. found an occurrence of a new caries pathology adjacent to glass ionomer restorations in primary molars at the 12th month recall in 10% of the re-
stored teeth and at 18 months of follow-up. All of the primary molars restored with compomer material had an excellent clinical assessment according to the criterion of “secondary caries”. The higher incidence of caries associated with glass ionomer restorations in primary teeth, according to the authors, depends more on the integrity of the restoration than on the type of material [26].

It is considered that larger restorations in primary teeth have a higher risk of secondary caries and less durability [27]. The results obtained from our study on the prevalence of caries associated with restorations in primary molars, in relation to the type of the affected surface, at the 6th and 12th month of the observation, do not fully correspond to the data in the literature were is reported mainly affection of the proximal surface restorations. Our results from the 18th month follow up were similar to those in other studies showing a higher incidence of secondary carious lesions in proximal restorations of temporary molars compared to occlusal surface obstructions [27].

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**CONCLUSIONS:**

A critical moment for the clinical condition of the primary molars restorations, regardless of the type of material and the affected surface, according to our study, is the 12th month after the treatment. The durability of restorations in primary molars in high-risk children was low, regardless of the type of material used. The strict implementation of individual preventive program, treatment protocol and proper selection of restorative material can reduce the relative share of clinically unacceptable restorations. The longevity of dental restorations of primary molars could be increased by applying alternative treatment approaches like polishing, sealing, repair of restoration. The FDI criteria for assessing the quality of dental restorations are objective, easily applicable and suitable for comparative scientific studies.

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