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Clinical Trial Concerning the Effectiveness of Two Types Dental Sealants in Children with Bruxism

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Abstract*. Dental sealants are important components of preventive dentistry. The aim of this clinical trial was to compare the effectiveness of an unfilled resin-based sealant and a carbomer-based dental sealant. 42 child patients with completely erupted inferior first molars and with diagnosed bruxism were included in the study. At 2 weeks, respectively 6, 12 and 18 months were evaluated the effectiveness of sealants after marginal deterioration, retention and the presence of caries. The results of the trial showed that unfilled resin-based sealant presented fewer modifications.*

Keywords*: resin-based sealant, carbomer-based sealant, clinical trial, bruxism*

1.Introduction

In modern dentistry, due to the fact that dental caries is one of the most frequent affections of teeth, the importance of prevention is extending [1]. Dental caries still remains a problem for many socio-economically deprived groups in all European Union Member States [2]. The prevalence of teeth decays diminished in the last years, including in Romania, due to the use of dental sealants [3-7].

Dental sealants are used for sealing the pits and fissures in lateral deciduous and permanent teeth [8] and are an important component in preventive dentistry, used for protecting the difficult-to-clean occlusal surfaces of the teeth from decay and to assess the caries risk in child patients, by forming mechanical barrier against cariogenic bacteria [9-11]. Sealants are classified into three types of materials: resin-based, glass ionomer based and polyacid-modified sealants [10]. The predominant types of sealant materials in the market at present are resin-based sealants and glass ionomer cement-based sealants [11]. Resin-based sealants and glass ionomer sealants are most commonly used as sealing materials [10].

The main components of *Clinpro sealant* (3M ESPE) (Figure 1A) [12], an unfilled resin-based sealant, are represented by ethylenedioxydiethyl dimethacrylate, bis-methacrylate, and propenoic acid. Is used together with Adper Prompt dental adhesive system (3M ESPE) that contains TEGDMA, BISGMA, respectively UDMA/bis-GMA monomers [13]. This sealant presents smart color-change technology and it turns from pink to natural tooth shade of color after curing. At the same time, it presents low viscosity in order to flow easily into pits and fissures, contains and releases fluoride, and adheres to the enamel [14].

Carbomer class of dental materials are basically glass ionomer-based materials, are used as dental sealants too, and present the property of gradual mineralization in fluorapatite [10,15,16]. *Glass Seal* (GCP Netherlands) (Figure 1B) [17] is a biocompatible glass carbomer sealant for permanent use, which contain enforced nano-glass, a nano-base fluoride alumino-silicate glass with mineral additions, a liquid silica supplement for high flexural, compressive strength, low solubility, and fluor/hydroxyapatite particles to start, aid and enhance the remineralization process by biofusion [15]. This material is suitable for sealing the pit and fissures of the permanent teeth, makes chemical connections with the dentin and the enamel, and presents remineralization action accelerated by the fluorapatite particles [18].

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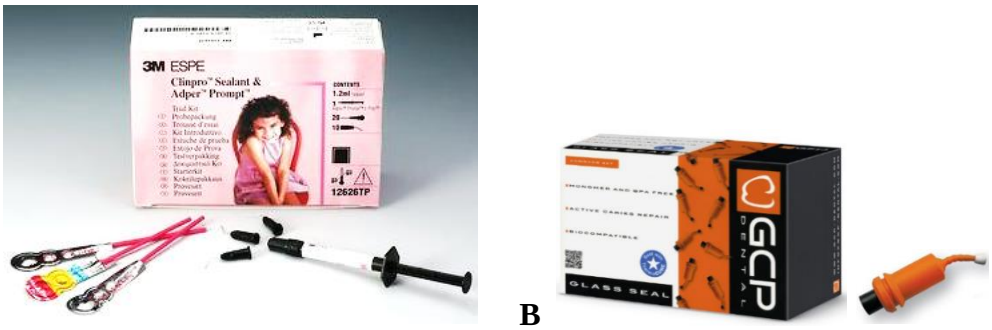

A **B**

Figure 1. Presentation mode of used materials in clinical trial:
A. Clinpro Sealant & Adper Prompt Self-Etch Adhesive Trial Kit – 3M [12];
B. Glass Seal – GCP [17]

Modified Ryge and Snyder criteria can be used for the clinical evaluation of the pit-and-fissure sealants [19,20].

Bruxism (*teeth grinding)* is defined as the repetitive jaw muscle activity characterized by the clenching or grinding of teeth [21]. After the studies of Yap, the diagnosis of bruxism includes the utilization of the subjective reports, the clinical examinations, and the oral trials [22].*Bruxism* in child patients is a minor problem that most kids outgrow. Bruxism can be determined by an abnormal bite, by teeth that are crooked or absent, and by stress, anxiety, or sleep disorders [23]. Child patients with teeth grinding often aren't aware of it, and frequently this problem is identified by parents or brothers.

The aim of this clinical trial was to evaluate and to compare the effectiveness from clinical view of Clinpro sealant (3M ESPE) resin-based sealant and Glass Seal (GCP Dental) carbomer-based dental sealant during two years, by using of modified Ryge and Snyder criteria.

2.Materials and method

42 child patients with bruxism, 19 boys and 23 girls, aged between 7 years and 4 months and 9 years and 6 months (mean age of 8 years and 5 months, ± 1 year and 1 month), and 84 totally erupted mandibular first molars were included in this study. The study was developed between January 2017 and October 2019.

The inclusion criteria of children were: a) child patients with erupted of both lower permanent first molars, that had indication for noninvasive technique for sealant application; b) absence of carious lesion on the first lower permanent molars; c) evidence of an acceptable dental hygiene at home; d) no fluoride mouth rinse program practiced in the school, or no central fluoride water supply in the school/community where the child patients live; e) good general health; f) no systemic diseases; g) no orthodontic appliances; h) children with bruxism; i) informed consent obtained from parents. Participants exclusion criteria were: a) children new erupted molars, or with hypo-plastic permanent first molars or with caries; b) patients undergoing fluoride application; c) long-term medication that could affect the salivary flow and diet modification; d) children with evidence of abnormalities in neurological, psychiatric, and any systemic diseases; e) children not sufficiently cooperative to applying the sealant and to return for the periodic check-up.

Before sealing, the parents and the young subjects were informed about the purpose of the study and the necessity of regular dental monitoring. Each child patient participated voluntarily and the parents signed the written informed consent. The child patients and the parents received instructions referring to the correct oral hygiene, through practical presentations regarding the correct teeth brushing.

The lower left permanent molar of each selected child patient was sealed with Clinpro sealant (3M ESPE), and the lower right molar with the carbomer-based sealant Glass Seal (GCP Dental). Both sealant materials were applied by strictly following the manufacturer's instructions. For Clinpro sealant placement, the used technique has completed the following steps [23]: cleaning of the occlusal

surfaces of debris with a rubber cup or a brush, with fluoride and oil-free prophy-paste; rinsing thoroughly with water; isolating the teeth and drying; applying the adhesive Adper Prompt Self-Etch adhesive to the entire sealed surface, by rubbing in the solution with moderate pressure for 15 seconds (proper bonding will not occur if the solution is simply applied and dispersed); using a gentle stream of air to thoroughly dry the adhesive to a thin film; applying the second coat of adhesive (does not need to be massaged into the surface); using a gentle stream of air to thoroughly dry the adhesive to a thin film; light-curing of adhesive for 10 seconds; stirring the sealant with the syringe-tip during or after placement, to help the elimination of any possible bubbles, and to enhance the flow into the pit and fissures; light-curing for the time period recommended by the producer (after light-curing, the color of Clinpro sealant material turns from pink to a natural tooth shade of color); removing with cotton pellets of the oxygen-inhibited surface layer, formed after light curing; checking the sealant coverage, the occlusion; instructing the patient to not expose the sealant to heavy pressure for about an hour.

The Glass Seal GCP sealant presentation mode is as capsules. For Glass Seal GCP sealant placement, the used technique goes through the following steps [24]: cleaning with a bristle brush of the occlusal surface by using fluoride-free agents, with a low-speed handpiece with irrigation, washing thoroughly with water, isolating with cotton rolls, air drying but do not desiccating, shaking the capsule; inserting the capsule into a universal capsule gun and clicking once to standardize; inserting the capsule into a mixer and mixing the capsule for 10-15 seconds with high frequency; removing the pin from the nozzle after mixing; inserting the capsule into the capsule gun and pulling the lever 2 clicks; extruding the Glass Seal GCP directly on the pit and fissure surface within maximum 15 seconds after mixing; ensuring that no air bubbles are included by using an instrument or a pellet/sponge with Gloss – GCP, for spreading a thin film on the sealed surface; light-curing of the Glass Seal for 60-90 seconds (overextending working time cause the loss of adhesion to the dental enamel and the dentin); instruction of the child patients to not expose the sealant to heavy pressure for about an hour. The etching of enamel is contraindicated for the Glass Seal GCP sealant. The light-cured biomaterial does not require rubber dam isolation.

For both light-cured sealants, the Expert FP-500 photo-polymerization lamp was used, which has the function of detecting caries too. The sealed area was checked with an explorer for the existence of voids, bubbles, or if the material is deficiently applied, in an attempt to remove the sealant, for complete coverage and retention. If complete re-sealing or additional sealant material was required, it was accomplished at that session. The excess sealing material was carefully removed, the occlusion was checked with articulating paper and corrected with finishing bur. Child patients and their parents received proper dental care instructions and practical demonstrations of the correct tooth-brushing with fluoride toothpaste.

The clinical evaluation of each sealed molars was performed at 2 weeks (reference line), at 6, 12 and 18-month follow-ups, by using a no. 05 explorer and concave mouth mirror. The external examiner, who was blinded to the used sealants, effectuated the clinical examination, the evaluation and the effectiveness of seals by using modified criteria of Ryge and Snyder (marginal characteristics, retention of the sealants, respectively the existence of caries). During patient follow-up, the restorations were not restored, only professional tooth cleaning procedures were performed.

The null hypothesis was that there is no significant difference between the two sealants regarding their effectiveness in child patients with bruxism.

The sealants were evaluated in terms of marginal deterioration, retention and the presence of caries. The used scores for evaluations were:

- For *marginal deterioration:* A=excellent margin with no evidence of crevice; B=discontinuity of the existing contour smaller than 50%; C=discontinuity of the existing contour greater than 50%, than unacceptable margin with larger crevice present.
- The *retention evaluation* of sealants: A=present, B=partially present, or C=lost.
- The *existence of decays*: P=present, or Ab=absent.

3. Results and discussions

The comparative results for both sealants, at reference line (2 weeks), 6 months, 12 months and 18 months are presented in table 1.

Table 1. Comparative results for the two sealants used in the clinical trial

Surface	Score	Clinpro ESPE sealant (31 sealed teeth)				Glass Seal GCP sealant (42 sealed teeth)			
		2 weeks	6 months	12 months	18 months	2 weeks	6 months	12 months	18 months
Marginal deterioration	A	**42** 100%	**42** 100%	**37** 88.09%	**33** 78.57%	**42** 100%	**42** 100%	36 93.54%	**31** 90.32%
	B	-	-	**5** 11.90%	**7** 16.66%	-	-	**5** 11.90%	**8** 19.04%
	C	-	-	-	**2** 4.76%	-	-	**1** 2.38%	**3** 7.14%
Retention	A	**42** 100%	**42** 100%	**38** 90.47%	**36** 85.71%	**42** 100%	**42** 100%	**36** 85.71%	**33** 78.57%
	B	-	-	**4** 9.52%	**5** 11.90%	-	-	**5** 11.90%	**6** 14.28%
	C	-	-	-	**1** 2.38%	-	-	**1** 2.38%	**3** 7.14%
Caries	P	-	-	**1** 2.38%	**3** 7.14%	-	-	**2** 4.76%	**4** 9.52%
	Ab	**42** 100%	**42** 100%	**41** 97.61%	**39** 92.85%	**42** 100%	**42** 100%	**40** 96.78%	**38** 90.47%

Marginal deterioration was observed in both sealants only in the third evaluation session, and the difference between the two types of sealant was in one sealing: the glass carbomer sealant presented in addition one of C class modification (=2.38%). In the fourth evaluation session, the difference between the two types of sealant was: the glass carbomer sealant presented 7.14% of C class modification in comparison with the resin-based sealant, which had 4.76%.

The *retention* evaluation of sealants showed that in the first (reference line, at 2 weeks) and second evaluation sessions (6 months) there were no differences. In the third evaluation session (after 12 months), the difference between the two types of sealant was: the glass carbomer-based sealant presented 11.90% of B class modification and 2.38% of C class modification comparing with the resin-based sealant, which presented only 9.52% B class modification. In the fourth evaluation session, the difference between the two types of sealant was of 3 sealings: the glass carbomer sealant presented 14.28% of B class modification (in comparison with 11.90% in the resin-based sealing), and 7.14% of C class modification (in comparison with 2.38% in the resin-based sealing).

The *existence of caries* was absent in the first and the second evaluation sessions. In the third evaluation session (after 12 months), the glass carbomer-based sealant presented 4.76% of decays, compared with 2.38% of the unfilled resin-based sealant. In the fourth evaluation session, the glass carbomer sealant presented 9.52% decays, in comparison with 7.14% of the resin-based sealing.

The results of the effectiveness evaluation in these two types of sealants, used in the sealing the first lower molars of child patients with bruxism, showed that although there were differences, they were not major. Unfilled resin-based sealant presented fewer modifications in the marginal integrity and in the retention during the assessments, compared with the carbomer-based sealant. At the same time, unfilled resin-based and carbomer-based sealants applied on occlusal surfaces of permanent lower molars were effective for preventing caries in child patients with bruxism. Restoration loss can be caused by the alteration of dentine binding, by the continuous flexion of the tooth, and by occlusal stress due by the bruxism.

Sealing is a protective method against the emerging of early caries by forming an interface between the dental surface and the oral environment [1]. Dental sealants represent an esthetic, non-invasive, and cost-effective procedure [8]. After the researches of Hassan and Mohammed [26], resin-based sealants accomplished better results than the glass ionomer-based sealants. Gorseta [27] states that the Glass Carbomer sealant presents similar retention rate with the resin-based sealants and suggests using

both materials in everyday practice. The success of sealing is determined by the monitoring and resealing if it is necessary because the incomplete sealing of pit and fissures can induce the hazard of caries apparition, alike to the never sealed teeth [10]. In the study of Barlean [28], 8.69% of the resin-based sealant was completely lost in the second year of assessment, compared to 78.26% of glass ionomer-based sealants. Assessment of composition and characteristics before choosing a sealant and their correct application increase the sealing results [29]. The disadvantages as sealing materials of resin-based sealants include polymerization shrinkage, with potentially microleakage [30]. In their review, Cvikl et al [31] specify that in cases when glass ionomer cement is used as a sealant, it presented the advantage of fluoride-releasing, but fractures of this type of material can occur due to their reduced ability to resist to the occlusal forces. The same authors underlined that the best advantage of resin-based sealing materials is their good durability, but the pronounced accumulation of biofilm occurs in resin-based materials.

4. Conclusions

Unfilled resin-based sealant presented fewer modifications in the marginal integrity and in the retention during the assessments, compared with carbomer-based sealant.

Unfilled resin-based and carbomer-based sealants applied on occlusal surfaces of permanent lower molars were effective for preventing caries in child patients with bruxism.

Further studies are required to evaluate the effectiveness of these sealant materials in child patients with bruxism.

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