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A Two-Year Clinical Evaluation of Fluoride and Non-Fluoride Resin-Based Pit-and-Fissure Sealants

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The aim of this study was to evaluate and compare for 24 months, the retention and surface characteristics of two pit-and-fissure sealants: Helioseal Clear and Helioseal F (Ivoclar Vivadent). The correlation between the different stages of eruption and sealant retention was also verified. Fifty children aged 6 to 8 years participated in the study, totalizing 153 teeth divided into two groups: HC (Helioseal Clear) and HF (Helioseal F). After 6, 12, 18 and 24 months, a clinical examination was performed by previously calibrated examiners. The surface characteristics and the retention of the sealants (modified RYGE & SNYDER criteria) were assessed. Analyzing the occlusal surface, HC exhibited a statistically significant higher retention at 12 (p=0.0345) and 24 months (p=0.0076). Concerning the surface characteristics, only the superficial discoloration of HC was smaller than HF, during the entire studied period. For all the other characteristics, the results of the Mann-Whitney test were highly significant at different periods (p=0.0000 to 0.0421). The frequency of air bubbles within the sealant surfaces, determined by Chi-square test, was significantly higher in HF (p=0.000:12 and 18 months to p=0.002: 6 and 24 months). HC sealant material exhibited the best performance regarding the retention and surface characteristics on the occlusal surface.

Key Words: pit-and-fissure sealants, pediatric dentistry, longitudinal studies, clinical trial.

Introduction

Although the occlusal surfaces of the permanent molars represent only 12.5% of all tooth surfaces (1-3), they are highly susceptible to caries (4-7), which accounts for more than two thirds of the total of lesions in children (1).

Sealing of pits and fissures is one of the most efficient methods to prevent occlusal caries (1,3,8-15). There is a great variety of materials available for this purpose: chemical or light-cured, opaque or transparent sealants, with or without filler and fluoride (3).

Resin sealants had four generations, according to their polymerization mechanism or composition. The first generation comprised materials activated by ultraviolet light, which are not available anymore; the second and third generations comprised self-cured and light-cured materials, respectively; and the fourth generation is of fluoride-containing materials (2).

The efficacy of resin-based sealants in preventing caries lesion has been associated with their retention (2,4,5,16), which decreases over time. This situation seems to be related to the prevalence of caries in the population. In the last decades, caries prevalence among children and adolescents seemed to decline in industrialized countries, but caries rate in occlusal surfaces is still high among this population (12,17). These differences may be due to the fluoridation of public water supply, use of fluoride dentifrices, and other factors. Considering this, it is not known whether the last sealant generation containing fluoride has actually added benefits to caries prevention (2).

Given the diversity of options and great clinical importance of sealing pits and fissures, as the tooth would be maintained sound in the long term, longitudinal studies are necessary to investigate the effectiveness of some available materials and techniques. The outcomes of these studies might determine the types of sealants that provide better protection against caries on occlusal pits and fissures, reaching a larger number of children who really need this type of preventive treatment. The reason to select these sealants was to test two materials with easy access to the dentists, besides the excellent results of resin-based materials. To the best of our knowledge, Helioseal Clear and Helioseal F (Ivoclar Vivadent) resin-based had never been compared in clinical studies before.

In this study, the retention and surface characteristics of two resin-based sealants with and without fluoride were evaluated and compared for 24 months. The correlation between the different stages of tooth eruption and the retention of the sealants was also verified.

Material and Methods

This study began after the approval of the institutional Ethics Committee (Process no. 139/2005). For sampling purposes, all children who looked for dental treatment at the Pediatric Dental Clinic of our School were invited to

participate. Considering the inclusion criteria and after granting verbal consent from the children and written consent from their parents, the sample was defined with 50 children of both sexes aged 6 to 8 years. They received the dental sealant within a 1-year period and the last evaluation was carried out after a period of 2 years from sealant placement. Inclusion criteria comprised: children with caries history, informed consent form signed by the parents or legal representative; presence of at least two recently erupted permanent first molars without structural alterations or caries lesions, either clinically or radiographically detected; good general health; no orthodontic appliances.

The teeth were selected after prophylaxis with air spray, water and sodium bicarbonate (Profident; Dabi Atlante S.A., Ribeirão Preto, SP, Brazil) and after taking 2 interproximal radiographs to evaluate the presence of occlusal and proximal caries lesions. The application of the sealant materials was performed at the same appointment. All the assessments were made after another dental prophylaxis, but the radiographs were only repeated at 12- and 24-month evaluations.

This study had a split-mouth design in which the permanent first molars of the same side received one sealant material type and the contralateral first molars received the other sealant material type. First, the mouth side (right or left) and then the material type were chosen using the Excel program from Windows®. The other sealant applications followed this initial choice. However, as the children would remain in the study for 2 years, it was decided to adopt a planned distribution where it was attempted to balance the amount of the first molars within the groups. Two materials were employed: Helioseal Clear® (HC; n=74 teeth) and Helioseal F® (HF; n=79 teeth) (Ivoclar Vivadent AG, Schaan, Liechtenstein), distributed among the permanent first molars.

Previous to sealant application, the stage of eruption of the selected teeth was evaluated by a 4-point scoring system using the criteria of Dennison; Straffon; Smith (8): 0=total eruption of tooth, with the distal marginal ridge above the gingival margin; 1=distal marginal ridge at the level of the gingival margin; 2=gingival operculum partially covers the distal marginal ridge; 3=the gingival operculum covers the distal marginal ridge.

The sealant applications were performed by a single operator, according to the manufacturer's instructions, under relative isolation with cotton rolls. The enamel was etched with 34% phosphoric acid (Dentsply Ind. e Com Ltd., Petrópolis, Rio de Janeiro, RJ, Brazil) for 15 s, copiously washed by water for 30 s and air dried. The sealant was applied on all pit and fissure system with the injector tip provided by the manufacturer. Next, the covered surface was evaluated to verify whether any air bubble appeared. If present, they were immediately removed with an explorer prior to light-curing of the material. After waiting 15 s for the material to flow, light-curing was performed for 30 s with a LED device (Ultraled; Dabi Atlante S.A., Ribeirão Preto, SP, Brasil).

At 6, 12, 18 and 24 months, the superficial characteristics and the retention of the sealant were evaluated for each group. For this purpose, two examiners previously calibrated for the use of the criteria modified from Ryge; Snyder (5) assessed the teeth (Table 1) and the air bubbles was evaluated by their presence in the sealed surface. For intra- and inter-examiner calibration were accepted Kappa values above 0.80. The assessment of the sealants was performed under relative isolation with cotton rolls, by an explorer and dental mirror, under dental spotlight, in conditions

Table 1. Criteria modified from Ryge and Snyder (5) for the clinical evaluation of the pit-and-fissure sealants

Surface characteristic	Score	Criteria
Marginal deterioration	Alfa (A)	Continuity of the existing contour
	Bravo (B)	Discontinuity of the existing contour smaller than 50%
	Charlie (C)	Discontinuity of the existing contour greater than 50%
Marginal discoloration	Alfa	Lack of discoloration
	Bravo	Margin discoloration
	Charlie	Discoloration under the sealant
Superficial texture	Alfa	Smooth equal to enamel
	Bravo	Slightly roughness
	Charlie	Surface roughness
	Delta (D)	Very rough and marked
Superficial discoloration	Alfa	Lack of discoloration
	Bravo	Light discoloration
	Charlie	Evident discoloration
	Delta	Marked discoloration
Retention classic technique	Alfa	Total retention
	Bravo	Partial retention with partial exposure of one fissure without risk to caries
	Charlie	Partial retention with partial exposure of one or more fissures with risk to caries
	Delta	Complete loss of the sealant

ideal for the examination.

The performance results in relation to the superficial characteristics and retention of the pit and fissure sealants were compared by the Mann-Whitney test. The comparison of the percentage of air bubbles on the sealant surfaces was evaluated by Chi-square test. Furthermore, the survival rate statistics of retention for both materials were assessed by Kaplan-Meier**.** The level of significance for all statistical tests was set at α=5%.

Results

One-hundred and fifty three permanent first molars of 50 children had sealants distributed into two groups: HC (n=74 teeth) and HF (n=79 teeth). After 6, 12, 18 and 24 months, 65, 58, 61 and 47 teeth, respectively were evaluated for HC group, resulting in a sample reduction of 36.5 % at 24 months. For HF group, the number of teeth evaluated during this period was 69, 65, 67 and 52, resulting in a sample reduction of 34.2 % at the end of the study.

The percentage of teeth distributed between the stages of eruption at the sealant application appointment for HC x HF were: 48.65% x 51.9%; 5.41% x 20.25%; 28.38% x 21.52% and 17.57% x 6.33% at 0, 1, 2 3 stages of eruption, respectively.

The performance in relation to the retention according to the criteria modified from Ryge Snyder (5), for both studied materials (HC X HF), at the four moments of clinical evaluation are in Table 2. HF showed the worst results at 12 and 24 months. The failures were about two times higher than HC at the same moments.

Throughout the study, the surface characteristics of HC were always higher than those of HF, as shown in Table 3.

The surface characteristics showed deterioration over time. However, at the end of the study most of the teeth exhibited scores A and B, considered as satisfactory (Table 3) for both materials.

Still regarding to the surface characteristics of the tested materials, HF showed the highest percentage of big air bubbles on the surface, as being 9.2% x 30.4%; 5.2% x 52.3%; 6.2% x 38.8% and 12.8% x 40.4% at 6, 12, 18, and 24 months respectively. The Chi-square test demonstrated that this difference was statistically significant at 6 months (p=0.002), 12 months (p=0.000), 18 months (p=0.000) and 24 months (p=0.002). Figure 1 shows examples of air bubbles formed on the occlusal surface of teeth sealed with HF, observed at 24 months.

The stage of eruption did not influence the retention success of the pit and fissure sealant materials (Table 4).

The mean survival time, in relation to the retention, of each sealant until the evaluation periods (in months) was 23.38 ($\pm$0.35) and 23.25 ($\pm$0.34) for HC and HF, respectively. The Kaplan-Meier survival curve of retention is shown in Figure 2. The comparison between two survival curves was not significant (Log rank test, p= 0.58).

Discussion

This longitudinal study highlighted some clinical aspects because of their importance in the preservation of the quality of pit and fissure sealant preventive treatment with time. The resin based sealant is often the choice material because it is cost-effective and of known aspects of its technique (18). For this reason, it was important to known if different resin based sealants with or without fluoride would have a better clinical performance in the long term. HC exhibited a significantly higher retention than HF after 24 months of clinical assessment. By analyzing the scores (A, B, and C), this superiority becomes evident with about double difference between the materials. HC also exhibited a smaller deterioration of the assessed surface characteristics, except for the surface discoloration. It is worth noting that regarding the presence of air bubbles, HC showed a significantly higher clinical behavior. Another important aspect when analyzing the longitudinal performance of the pit and fissure sealant material is to assess the influence of the stage of eruption on the retention success (Table 4). It was observed that this fact did not interfere in the results.

HC exhibited a total retention percentage of 77.6% after 12 months and of 66.0% after 24 months, which are closer to the results of 80% and 71%, respectively reported by Ripa (4). HF showed worse results of 55.4% and 34.6% of total retention at the same moments, respectively (Table 2). Accordingly, HF failure was more frequent. It is important to stress that this failure was in

Table 2. Behavior regarding the retention on the occlusal surface for both materials during the study.

Criteria (%)	Groups							
	6 Months		12 Months		18 Months		24 Months	
	HC	HF	HC	HF	HC	HF	HC	HF
Alfa (A)	83.1	76.8	77.6	55.4	65.6	53.7	66.0	34.6
Bravo (B)	15.4	21.7	20.7	41.5	31.1	37.3	25.5	50.0
Charlie (C)	1.5	1.5	1.7	3.1	3.3	9.0	8.5	15.4
Delta (D)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
p value	0.5402		0.0345 †		0.1918		0.0076 †	
Success	98.5	98.5	98.3	96.9	96.7	91.0	91.5	84.6
Failure	1.5	1.5	1.7	3.1	3.3	9.0	8.5	15.4

*Success (A+B). Failure (C+D). †= Significant (Mann-Whitney test).

relation to the partial retention, which could put the tooth at caries risk, because no material was lost at 24 months. Morphis and Toumba (12) also found worse retention results for pit and fissure sealants containing fluoride in their composition 1 year after their application. They obtained a retention result of 67.74% for Delton Plus, a sealant containing fluoride (sodium fluoride associated with barium fluoroaluminosilicate glass), while the retention results for Delton was of 70.00%. Notwithstanding, Jensen et al. (19) compared Fluroshield (containing 2% sodium fluoride) with an analogous pit and fissure sealant without fluoride (Prismashield) and obtained higher retention values with better results for the sealant containing fluoride. The retention of the pit and fissure sealants in the permanent first molars, 12 months after their application was 86.9% for the material containing fluoride and 80.05% for the conventional material.

The retention of the pit and fissure sealant is of great interest because the material effectiveness is related to its bonding to the enamel surface (3,16). Most of the failures occur within the first year after the application of the sealant, with a loss rate estimated in 5-10% per year (10). In this study, the failure rate of the first two assessments was 3.2% and 4.6%, respectively for HC and

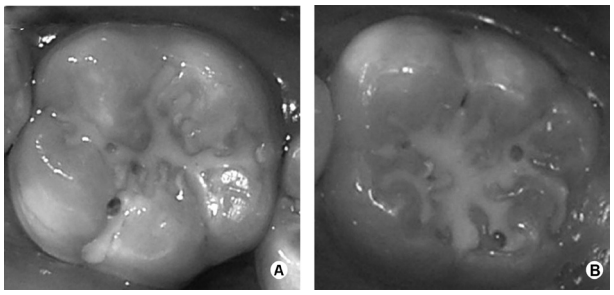

Figure 1. Air bubbles formed on the occlusal surface of HF at 24 months.

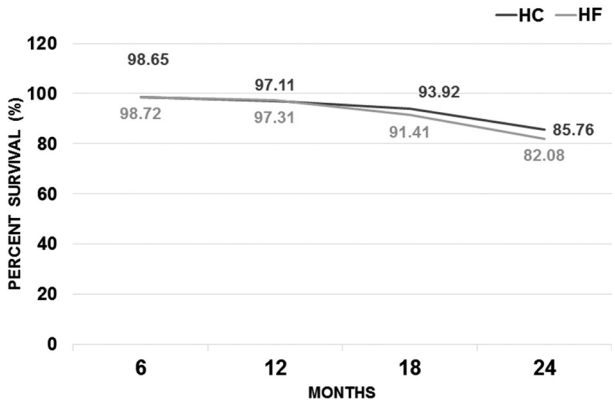

Figure 2. Kaplan-Meier survival curve of retention for both materials during the study.

Table 3. Behavior regarding the occlusal surface characteristics for both sealants during the study

Criteria (%)	Marginal deterioration								Marginal discoloration							
	6 m		12 m		18 m		24 m		6 m		12 m		18 m		24 m	
	HC	HF	HC	HF	HC	HF	HC	HF	HC	HF	HC	HF	HC	HF	HC	HF
Alfa	55.4	15.9	55.2	24.6	19.7	7.5	12.8	7.7	87.7	37.7	84.5	43.2	91.8	34.3	87.2	32.7
Bravo	44.6	84.1	44.8	75.4	80.3	91.0	85.1	90.4	10.8	59.4	15.5	53.8	6.6	61.2	10.6	67.3
Charlie	0.0	0.0	0.0	0.0	0.0	1.5	2.1	1.9	1.5	2.9	0.0	3.1	1.6	4.5	2.1	0.0
p value	0.0001†		0.0033†		0.1918		0.6832		0.0000†		0.0000†		0.0000†		0.0000†	
Criteria (%)	Surface texture								Surface discoloration							
	6 m		12 m		18 m		24 m		6 m		12 m		18 m		24 m	
	HC	HF	HC	HF	HC	HF	HC	HF	HC	HF	HC	HF	HC	HF	HC	HF
Alfa	56.9	43.5	50.0	26.2	60.7	35.8	72.3	53.8	64.6	97.1	60.3	90.8	88.5	100	70.2	86.5
Bravo	40.0	36.2	46.6	43.1	34.4	26.9	25.5	26.9	35.4	2.9	32.8	7.7	9.8	0.0	27.7	13.5
Charlie	1.5	13.0	3.4	30.8	3.3	25.4	0.0	1.9	0.0	0.0	6.9	1.5	1.6	0.0	2.1	0.0
Delta	1.5	7.2	0.0	0.0	1.6	11.9	2.1	17.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
p value	0.042 †		0.0004†		.0003†		0.0507		0.0001†		0.0000†		0.2653		0.1565	

†=Significant (Mann-Whitney test).

HF (Table 2), slightly below that observed by Dennison et al. (8). However, according to these authors, the moment of highest failure would occur within the first 6 months after the application. Unlikely, in this study, the failures were observed 6 months after the application of both HC and HF (1.5%). The failures became more evident at the third assessment, with HF showing the worst results (Table 2). Nevertheless, considering the survival rate both sealants presented similar retention performance (Fig. 2). It must be emphasized that the air bubbles that became evident during the study were mostly localized in the body of the sealant and not marginal to them.

As sealant placement is mainly indicated for young teeth, it is important to assess the influence of the level of eruption on the retention of the material. Dennison et al. (8) associated 5 stages of tooth eruption with sealant retention and verified that, after 36 months, the teeth where sealant had been placed during the stages corresponding to 2 and 3 in their study presented a 46.4% success rate *versus* a 36% success rate observed in the present study after 24 months. Sealant placement during the stage corresponding to 1 in their study resulted in a 74.2% success rate compared with a 10.11% success rate observed in the present study. These results indicate that the application of sealants in partially erupted teeth leads to a high risk of failure. During the initial stages of eruption is almost impossible to avoid that the gingival fluid contaminates the area to receive the sealant because the fluid invades the occlusal surface by capillarity after air drying. It is actually a very common situation that challenges sealant placement. When the gingival operculum covers the distal marginal ridge of the occlusal surface, there is a twice greater chance of retreatment need than when the occlusal surface is totally exposed (8).

In this study, we analyzed the stage of eruption as favorable or unfavorable and associated it with sealant retention (success and failure). A favorable eruption would be related to those stages in which the clinical crown is already exposed to the oral environment and enables the isolation without great risk of contamination. Retention was considered as successful when there was no need of repairing the sealant, including those with losses that did not expose the tooth surface to caries risk. Unlikely Dennison et al. (8), we observed that the stage of eruption did not influence sealant retention. It should be highlighted that the samples were matched regarding to the stage of eruption. Both materials are resin-based sealants, which have exhibited very high levels of retention over time, as demonstrated by the literature. Notwithstanding, the results can be justified by the extremely accurate technique during the application of the materials on etched enamel, very well dried and without contamination, even when the clinical situation was unfavorable. Pit-and-fissure sealant application is a sensitive and meticulous technique where the ability of the operator is an important contributing factor (12, 20). The operator's experience and the accurate technique are critical factors for the longevity of the material.

Most of the surface characteristics of HC were higher than those of HF, especially at the 6 and 12 month assessments (Table 3). HF showed much more marginal fractures and material loss, while HC exhibited a more homogenous wear without exposing irregular margins. These observations are in agreement with those of Ganss et al. (9), who highlighted that the surface roughness and the lack of marginal adaptation contributes for the bacterial plaque accumulation, as well as those of Koch et al. (21) who reported that materials with fillers have a significantly higher deficiency in the marginal adaptation than those without fillers. HC only exhibited a significant result concerning the marginal discoloration, with higher percentage of score A in all evaluations (Table 3). This was attributed to the aforementioned discussion regarding the small marginal fractures observed for the HF material. They resulted in acute and irregular margins exposed to the oral environment. Therefore, the bacterial plaque accumulation that is commonly seen on the permanent first molars of children within the age studied range probably contributed for the pigment accumulation on those areas. The marginal discoloration of HF was also observed by Ganss et al. (9). These authors reported that HF compared with Fissurit F exhibited a greater number of teeth with marginal discoloration one year after its application. Concerning to the marginal discoloration of HC, the results of this study were worse than those of Oliveira et al. (22). These authors did not observe marginal discoloration of Delton pit and fissure sealant under relative isolation at the 6- and 12-month assessments, while this study showed a mean of 86.1% of teeth without marginal discoloration (Table 3).

It is worth noting that the surface texture accounted for the highest percentages of HF cases classified as scored

Table 4. Behavior regarding to the retention on the occlusal surface at 24 months for HC material in relation to the stage of eruption at the sealant placement

Stage of eruption	Sealant retention (%)	
	Success	Failure
Unfavorable (2+3)	100	0
Favorable (0+1)	84.62	15.38
p value	0.117	

*Success=Alfa + Bravo; Failure=Charlie + Delta. Statistical analysis by Fisher's exact test.

D, that is, cases which should be repaired at 6, 18 and 24 months (Table 3). At the last two assessments, an evident degradation of the material was also observed. We believe that this was due to the surface wear promoted by the functional occlusion. Although this fact made disappear some irregularities, it also resulted in more intense irregularities, exhibiting a high frequency of voids within HF (Fig. 1). Approximately 30% of HF teeth exhibited voids at the first assessment. At 12 months, an increase of 20% in the number of sealants with air bubbles was verified. From that moment on, there was stabilization around 40%. It is likely that the high number of voinds could have occurred in consequence of the injector tip of HF. It was observed that the HF tip has greater diameter than that HC. After the material use, the syringe's plunger was always pulled back. Although a small amount of the material was dispensed prior to the next application, the diameter of the injector tip of HF may account for the greater air injection within this material, consequently leading to the formation of air bubbles. This superficial defect occurrence was also verified in the study of Ganss et al. (9), who observed the inclusion of air bubbles in about 10% of the cases for HF and Fissurit F sealants. Notwithstanding, HF showed little air inclusion compared with Fissurit F, which is not in agreement with this present study. It is important to note that during HF application, the inclusion of air bubbles was very common, which were removed prior to light-curing. Thus, all air bubbles identified at the 6-month evaluation were located within the material at the application appointment, and over time, with the sealant wear, they were exposed. The results obtained at the 6-, 12- and 24-month evaluations, seemed to demonstrate that, over time, there would be an increase in the number of air bubbles through the wear of the thin layer of the material covering them, therefore leading to their exposure. At 18 months, there was apparently a decrease in their number. This could also be explained by the wear of the material, which would make them disappear when they were located very superficially. These observations corroborate the findings of Sundfeld et al. (23,24), who claimed that it is possible to detect, over time, an overview alteration of the surfaces of the sealants by either the appearance or even disappearance of the superficial air bubbles. This findings demonstrate the existence of the occlusal wear of the sealant material as the teeth are positioned in the dental arch by the movements of eruption and articular accommodation.

Tooth discoloration was not significantly different when both materials were compared in the last assessments (Table 3). Notwithstanding, HF always showed a better surface appearance than HC. The presence of both a white pigment and filler in HF makes this material less porous and therefore more resistant to the incorporation of external pigments from the oral environment. Over time, HC exhibited a yellowish color and superficial opacity probably because it is a transparent material without filler and therefore more porous. However, this surface characteristic was stable up to the final assessment.

Other caries prevention methods have been studied (25). Chen (26) compared resins and glass ionomer cements used as sealant materials and observed that only 20% were lost after 24 months. The study comparing resin-modified glass ionomer cements to resins at 36 months, observed better complete retention rates for resins (94% x 5%) (27). The results are similar to the present study. On the other hand, a complete retention rate observed by Barja-Fidalgo (28) for resins was 29% and for glass ionomer cements of 21% at 5 years.

Further studies on HF pit and fissure sealant are required to confirm or reject the hypothesis its injector tip diameter caused the formation of air bubbles that contributed to the negative results obtained with this material.

The results of this study showed that HC a better clinical behavior than HF regarding to the retention to occlusal pits and fissure, marginal discoloration and presence of air bubbles in the material. All these characteristics make the material more suitable to the prevention of dental caries for recently erupted first molar.

Resumo

Os objetivos deste trabalho foram avaliar e comparar por 24 meses, a retenção e as características superficiais de dois diferentes materiais seladores, Helioseal Clear e Helioseal F(Ivoclar Vivadent). A correlação entre os diferentes graus de erupção e a retenção dos selantes também foram verificadas. Cinquenta crianças de 6 a 8 anos de idade participaram deste estudo, totalizando de 153 dentes divididos em dois grupos: HC (Helioseal Clear) e HF (Helioseal F). Após 6, 12, 18 e 24 meses, avaliação clínica foi realizada por dois examinadores calibrados. As caracterísiticas superficiais e a retenção (critério modificado de Ryge &tSnyder) foram avaliadas. A análise da superfície oclusal, o HC demostrou retenção estatisticamente significante maior para os 12 meses (p=0,0345) e 24 meses (p=0,0076). Em relação às características superficiais, somente para descoloração superficial, o HC foi menor que do HF, durante o período estudado. Para as demais características, os resultados do teste de Mann-Whitney foram altamente significantes para HC em diferentes períodos (p=0,0000 a 0,0421). A frequência de bolhas nas superfícies seladas, determinada pelo teste do Qui-quadrado, foi maior e mais significante no HF (p=0,000:12 e 18 meses a p=0,002: 6 e 24 meses). O selante HC apresentou melhor desempenho à retenção e características superficiais.

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