

# Comparison and Evaluation of the Retention, Cariostatic Effect, and Discoloration of Conventional Clinpro 3M ESPE and Hydrophilic Ultraseal XT Hydro among 12–15-year-old Schoolchildren for a Period of 6 Months: A Single-blind Randomized Clinical Trial

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## ABSTRACT

**Introduction:** Pit and fissures are more prone to caries as compared to smooth surfaces. Sealing the pit and fissures with sealants is considered to be highly effective in the prevention of pit and fissure caries. Hydrophobic sealants are technique sensitive in nature. Ultraseal XT Hydro sealant is moisture tolerant which incorporates the benefits of both hydrophilic and hydrophobic sealants into one unique chemistry. Hence, the study was conducted to compare and evaluate the retention, cariostatic effect, and discoloration of conventional Clinpro™ 3M™ ESPE™ and hydrophilic Ultraseal XT Hydro sealants among 12–15-year-old schoolchildren for 6 months.

**Materials and methods:** It was a single-blinded, randomized split-mouth clinical trial. Schoolchildren aged 12–15 years were recruited in this clinical trial. Clinpro sealant and Ultraseal XT Hydro were placed in the right and left quadrant molars, respectively, and were assigned as group I and II. The sample size arrived was 60 teeth per group and at 30 patients based on the computer-generated random sequence. Sealant coverage between the two sealants was compared using Mann–Whitney test and Z test for proportions.

**Results:** After 6 months, it was seen that 10 teeth out of 44 (22.72%) with Clinpro had the sealant covering all the fissures compared to Ultraseal XT Hydro which was only 9%. Fifty-nine percent of retention rate was seen with Clinpro compared to Ultraseal XT Hydro sealant (27.27%). Caries incidence was higher in the case of group II. No difference was observed with regard to the discoloration of the sealants.

**Conclusion:** It was concluded that for a longer follow-up period conventional Clinpro™ 3M™ ESPE™ was better than Ultra XT Hydro seal in terms of retention and cariostatic effect.

**Keywords:** Clinpro, Retention, Split-mouth trial, Ultraseal XT Hydro.

*International Journal of Clinical Pediatric Dentistry* (2020): 10.5005/jp-journals-10005-1859

## INTRODUCTION

One of the most frequently occurring oral health problems among children is dental caries.<sup>1</sup> It is a microbial disease that is caused by the activity of the bacterial biofilm due to the breakdown of food particles and the production of acid, which in turn leads to the dissolution of tooth enamel.<sup>2</sup>

A pit is a hollow or an indentation found at the junction of developmental grooves. A fissure is a deep opening or slit between adjacent cusps.

Ninety percent of the carious lesions occurring in permanent posterior teeth involve the pit and fissures.<sup>3</sup> Surfaces of the tooth having deep pits and fissures are more likely to develop occlusal caries.<sup>4</sup> Food particles are trapped within the deep grooves which subsequently leads to the formation of dental caries. Hence, such pits and fissures need to be sealed with a dental material that seals them completely.

Sound teeth without any sign of discoloration or caries should be considered for placing a sealant. The surface of the tooth should have no sign of occlusal or proximal caries.<sup>5</sup>

According to Simonsen, pit and fissure sealant is a material that is placed in the pits and fissures of caries susceptible teeth.<sup>6</sup> It forms a micromechanical layer between the tooth surface

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**How to cite this article:** Mohapatra S, Prabakar J, Indiran MA, *et al.* Comparison and Evaluation of the Retention, Cariostatic Effect, and Discoloration of Conventional Clinpro 3M ESPE and Hydrophilic Ultraseal XT Hydro among 12–15-year-old Schoolchildren for a Period of 6 Months: A Single-blind Randomized Clinical Trial. *Int J Clin Pediatr Dent* 2020;13(6):688–693.

**Source of support:** Nil

**Conflict of interest:** None

and, caries-producing bacteria, thus preventing the fermentation of tooth enamel.<sup>6</sup>

Fluoride application and other caries prevention techniques are less effective as compared to pit and fissure sealant placement.<sup>3</sup> Sealants can prevent and stop the progression of pit and fissure

caries in children as compared to the use of other techniques. They also minimize the progression of occlusal caries. Hence, pit and fissure sealants are the most effective in preventing dental caries.

In recent years, different types of resin-based materials are available in the market. The materials vary from each other according to filler content, method of polymerization, and fluoride-releasing ability of the material.

The effectiveness of a resin-based sealant depends primarily on retention and secondarily on the cariostatic effect of the sealant. The retention of a resin-based sealant is poor when contaminated with moisture.

Hence, a sealant that is moisture friendly—Ultra seal XT Hydro, has been introduced. Ultraseal XT Hydro sealant is a light-cured, fluoride-releasing material with thixotropic properties. The benefits of both hydrophilic and hydrophobic sealants are incorporated into it. Upon placement, its hydrophilic nature helps in its easy flow into the fissures in the presence of saliva. It is tough and durable as it is resistant to water absorption and degradation similar to hydrophobic sealants.<sup>7</sup> Ultraseal XT Hydro sealant has fluorescent properties because of which the examiner can check its retention at the time of placing it and at follow-up visits.<sup>7</sup>

In the present study, a comparison has been done between Ultraseal XT and conventional Clinpro 3M ESPE sealant. Several *in vivo* studies have been conducted to study the properties of Clinpro 3M ESPE sealant and compared with different sealant materials<sup>8,9</sup> but no study has compared the properties of these two sealants. Hence, this study aimed to compare and evaluate the retention, cariostatic effect, and discoloration of conventional Clinpro™ 3M™ ESPE™ and hydrophilic Ultraseal XT Hydro among 12- to 15-year-old schoolchildren for 6 months.

## MATERIALS AND METHODS

### Study Design

Single-blinded, randomized split-mouth clinical trial.

### Study Population

Schoolchildren aged 12–15 years of Mahatma Gandhi Higher Secondary School, Chennai, Tamil Nadu.

### Inclusion Criteria

- Healthy schoolchildren without any known history of systemic illness.
- Children with dmft <2.
- Cooperative children.

### Tooth Selection for Sealant Placement

Fully erupted maxillary and mandibular permanent 1st or 2nd molar having occlusal fissures with functional occlusion.

### Exclusion Criteria

- Children having any signs of dental caries.
- Uncooperative children.

### Sample Size Determination

Based on a study conducted by Kumaran,<sup>9</sup> the sample size arrived at 30 patients with 60 teeth per group.

### Ethical Clearance

Ethical clearance was obtained from the Institutional Ethics Committee, Saveetha Dental College and Hospitals, Saveetha

Institute of Medical and Technical Sciences before the study (STP/SDMDS13PHD43). Since the study was conducted in an orphan school, written informed consent was obtained from the headmaster of the school as well as the study participants. The identity of the participants was not disclosed.

### Randomization and Blinding

Simple randomization using a computer-generated table was used to assign one sealant for the right molar tooth. An alternate sealant was placed on the left molar. Randomization was done by a third person who was not aware of the study. The random number generated was only disclosed to the clinician before the sealant placement procedure. The assessor was blinded to the sequencing and allocation of the groups.

### Calibration of Examiner and Assessor

A series of clinical training was given to the examiners in the Department of Public Health Dentistry, Saveetha Dental College, Chennai, before the study. Inter-examiner reliability was calculated by examining and re-examining a group of 25 schoolchildren at least 30 minutes after the initial examination. The  $\kappa$  coefficient for examiners was 0.78 and for assessors, it was 0.75.

### Armamentarium

The following instruments/materials were used for the study:

The portable dental unit, tray sheet, disposable head cap, disposable mouth mask, disposable gloves, disposable cups, plane mouth mirror, Williams periodontal probe, Tweezer, pumice, cotton rolls, etchant (37% orthophosphoric acid), Clinpro 3M ESPE, Ultraseal XT, hydro, light-curing unit, performa.

### Sealant Placement

Two operators received training for sealant placement so that there is minimal variation in the treatment protocol.

Table of random numbers determined which material will be used to seal which side of the mouth. Scaling was done on the occlusal surface of the teeth to remove deposits and food debris. Clinpro was placed on one side of the mouth and Ultraseal XT hydrophilic sealant was placed on the other side (Table 1).

Thirty-seven percent of phosphoric acid was used to etch the occlusal surfaces of molars. The surfaces were etched for 15–20 seconds, rinsed with water, and then dried using a 3-in-1 syringe. A LED curing light was then used for 20 seconds to cure the resin sealants. Complete retention of sealants was checked using a probe and occlusion was checked using an articulating paper.

**Table 1:** Products tested and its composition

| Material             | Group I Clinpro   | Group II Ultraseal XT Hydro  |
|----------------------|---|--|
| Type                 | Unfilled resin based  | 53% highly filled resin based  |
| Principal ingredient | Triethylene glycol dimethacrylate, BISGMA, tetrabutylammonium tetrafluoroborate, dichloride methylsilane, silica, dye | Triethylene glycol dimethacrylate, diurethane dimethacrylate (DUDMA), aluminum oxide, methacrylic acid, titanium dioxide, sodium monofluorophosphate |
| Manufacturer         | 3M ESPE   | Ultradent  |

## Outcome Assessment

All the cases were clinically evaluated after 6 months of application. The primary outcome was sealant retention and the secondary outcome was discoloration and cariostatic effect. The retention rate was assessed using the color, coverage, and caries (CCC) sealant evaluation system described by Deery.<sup>10</sup>

Criteria for sealant coverage is described as follows:

- A—All fissures covered with a sealant.
- B—>50% of fissure covered with a sealant.
- C—<50% of fissure covered with a sealant.
- D—No sealant present.

Coding for dental caries:

- 0—Surface sound.
- 1W—White spot enamel carious lesions.
- 1B—Brown spot enamel carious lesions.
- 2—Demonstrable loss of tooth structure.

Discoloration:

- Presence or absence of discoloration of sealant.

## Statistical Analysis

Data were entered in a Microsoft excel sheet and analysis was done using SPSS software (version 20). Numerical data were presented as percentages. Retention of sealant was compared by the Mann–Whitney test and z test for the proportions between the two sealants. A *p* value of <0.05 was considered statistically significant.

## RESULTS

Thirty children (12–15 years) were included in the study out of which eight children (four from each group) had left the school in the follow-up visit (Flowchart 1).

21.4 and 28.6% of right maxillary and mandibular first molar of group I (*n* = 28) showed sealant present on all the fissures. On the other hand, 14.3% of both left maxillary and mandibular first molar of group II (*n* = 28) showed sealant present on all the fissures. 14.3%

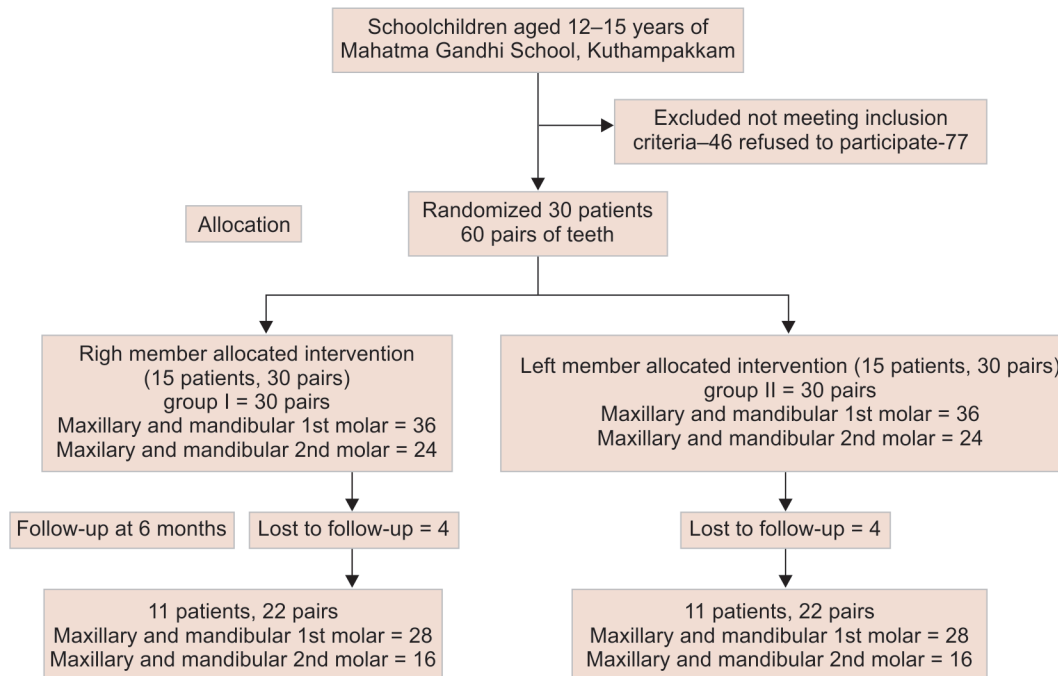
of both maxillary and mandibular first molar of group I showed sealant present on >50% of fissures but some were missing whereas 7.1% of group II mandibular first molar showed code B. 28.6% of right maxillary first molar and 21.4% of a right mandibular first molar of group I showed sealant present on <50% of fissures whereas left maxillary first molar of group II showed 21.4% and mandibular first molar showed 7.1%. 35.7% of both group I maxillary and mandibular first molar and 64.3 and 71.4% of group II maxillary and mandibular first molar showed a code of D which indicates no sealant present.

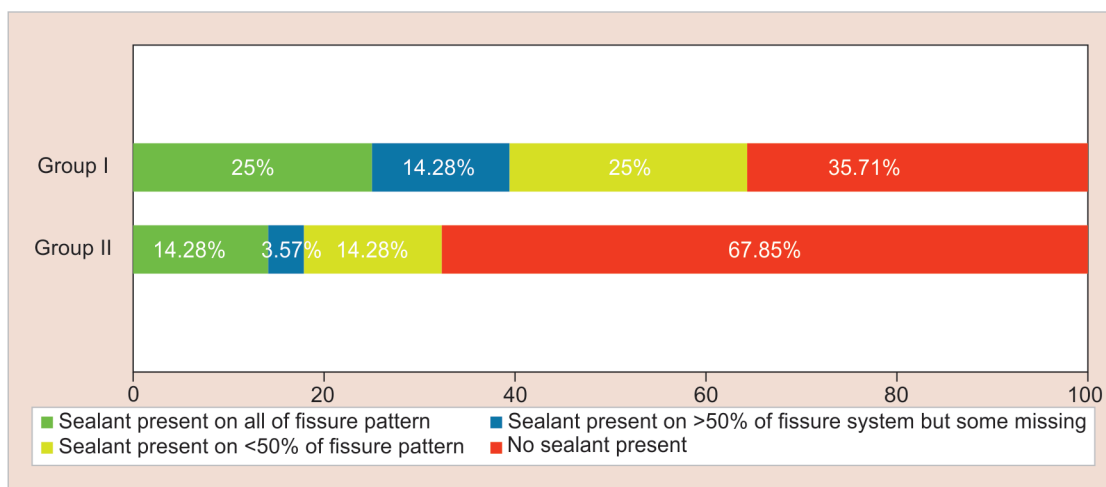
12.5 and 25% of right maxillary and mandibular second molar of group I (*n* = 16) showed sealant present on all of the fissures. On the other hand, 12.5 and 0% of the left maxillary and mandibular second molar of group II (*n* = 16) showed sealant present on all of the fissures. 12.5% of both group I showed sealant present on >50% of fissure pattern but some missing. 25 and 12.5% of right maxillary and mandibular first molar of group I showed sealant present on <50% of fissure pattern, whereas left maxillary and mandibular second molar of group II showed 12.5%. Fifty percent of group I and 75 and 87.5% of group II maxillary and mandibular molar showed a code of D which indicates no sealant present.

Figure 1 shows the comparison of sealant coverage (retention) of group I and group II sealants in the maxillary and mandibular first molar after 6 months of sealant placement. Twenty-five percent of group I showed sealant present on all the fissures as compared to group II which was found to be only 14.28%. 67.85% of group II showed a code of D as compared to group I which was found to be 35.71%. Sealant coverage (retention) of group I was found to be significantly higher compared to group II sealant in maxillary and mandibular second molar after 6 months of sealant placement using Mann–Whitney *U*-test (*p* < 0.05).

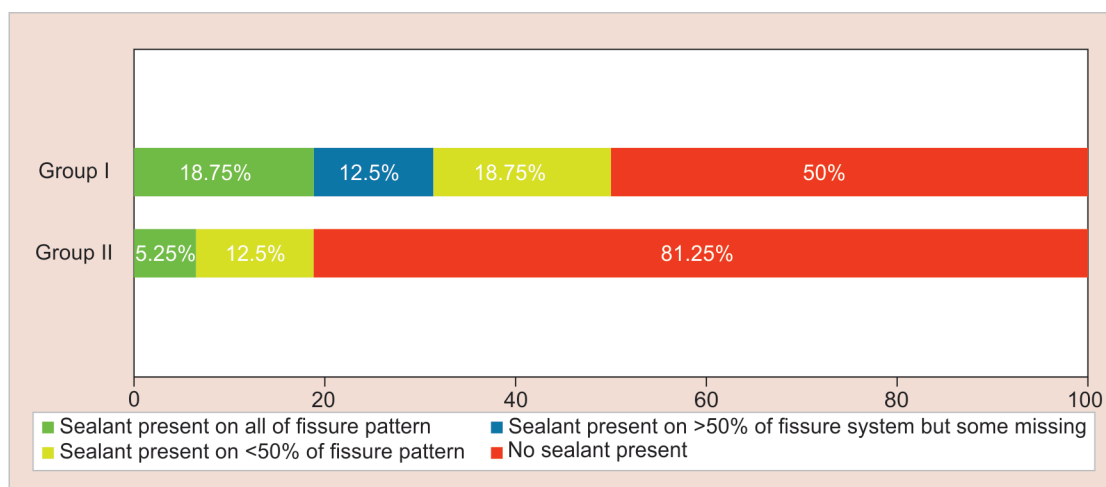
Figure 2 shows the comparison of sealant coverage (retention) of group I and group II sealants in the maxillary and mandibular second molar after 6 months of sealant placement. 18.75% of group I teeth showed sealant present on all the fissures as compared to group II which was found to be 6.25%. 81.25% of group II showed a

Flowchart 1: Flowchart of study





**Fig. 1:** Comparison of sealant coverage (retention) of group I and group II sealants in maxillary and mandibular first molar after 6 months of sealant placement. Mann–Whitney *U*-test—266.000 ( $p < 0.05$ )



**Fig. 2:** Comparison of sealant coverage (retention) of group I and group II sealants in maxillary and mandibular second molar after 6 months of sealant placement. Mann–Whitney *U*-test—85.500 ( $p < 0.05$ )

code of D as compared to 50% of group II which indicates no sealant present. Sealant coverage (retention) of group I was found to be higher compared to group I sealant in maxillary and mandibular second molar after 6 months of sealant placement using Mann–Whitney *U*-test but it was not statistically significant ( $p = 0.058$ ).

Table 2 shows the comparison of sealant coverage (retention) of group I and group II. Ten (22.7%) teeth of group I showed sealant present on all the fissures when compared to five teeth (11.4%) of group II. Eighteen (40.9%) teeth of group I had no sealant present as compared to 32 (72.7%) teeth of group II. The difference was statistically significant ( $p < 0.05$ ).

Two teeth in group I had white spot enamel carious lesions and two had brown spot enamel carious lesions. In group II, two teeth had white spot enamel carious lesions and three teeth had brown spot enamel carious lesions. None of the sealants showed discoloration and there was no difference observed between the two sealant materials.

## DISCUSSION

Pit and fissures are more prone to dental caries as compared to smooth surfaces because of complex morphology and lack of saliva access to the fissures.<sup>11,12</sup>

Hence, the most effective way to prevent pit and fissure caries is by sealing them with sealants.<sup>13</sup> Commercially available sealants are hydrophobic in nature. Their application is affected by the patient's cooperation, operator's skills, and lack of moisture control, making the procedure technique-sensitive.<sup>14,15</sup> Also, extreme sensitivity to moisture makes it difficult to etch partially erupted molars.<sup>16</sup> Hence, moisture friendly sealants have been developed which will not be affected by moisture contamination.<sup>17</sup>

Ultraseal XT is one such pit and fissure sealant which has combined the benefits of both hydrophilic and hydrophobic sealants into one sealant. It is moisture-friendly due to its hydrophilic nature and durable due to its hydrophobic nature.

**Table 2:** Comparison of sealant coverage (retention) of group I and group II

| Evaluation | Sealant coverage  | Group I (n = 44) |      | Group II (n = 44) |      | Significance |        |
|------------|---|------------------|------|-------------------|------|--------------|--------|
|            |   | n                | %    | n                 | %    | Z value      | p      |
| 6 months   | A—Sealant present on all of fissure system                    | 10               | 22.7 | 5                 | 11.4 | 1.66         | 0.197  |
|            | B—Sealant present on >50% of fissure pattern but some missing | 6                | 13.6 | 1                 | 2.3  | 3.57         | 0.059  |
|            | C—Sealant present on <50% of fissure pattern                  | 10               | 22.7 | 6                 | 13.6 | 1.00         | 0.317  |
|            | D—No sealant present  | 18               | 40.9 | 32                | 72.7 | 3.92         | 0.048* |

z-Test for proportions ( $p < 0.05$ )

\*Statistically significant

It is a 53% highly filled resin with thixotropic properties which increases the bond strength with the tooth. Therefore, higher bond strength results in reduced microleakage and increased marginal retention.<sup>7</sup> Hence, this present clinical trial was taken up to compare the effectiveness of conventional Clinpro 3M ESPE and Hydrophilic Ultraseal XT Hydro sealants.

The effectiveness of a sealant is measured through its retention.<sup>6,18</sup> If there is a good, strong bond between the sealant and the tooth, caries incidence is expected to reduce.<sup>18</sup> The outcome measures assessed in the present study are retention, caries incidence, and discoloration.

It is difficult to evaluate the retention of sealants at follow-up visits since there is no standardized method to assess the retention coverage.<sup>19</sup> Most studies<sup>20–23</sup> use Simonsen criteria for assessing the sealants. But Simonsen's criteria do not record dental caries and surface coverage of sealants. Deery in 2001<sup>10</sup> gave the CCC sealant evaluation system which records dental carries and surface coverage of sealants. Hence, this evaluation system has been used in this study.

Half-mouth designs have been used in most of the studies in which one side of the mouth receives treatment and the other half of the mouth does not receive any treatment.<sup>24–26</sup> However, it is unethical to use untreated teeth as controls. Hence, a split-mouth design was used in which every child received group I and group II sealants on both sides of maxillary and mandibular permanent molars.

Retention of light-cured fissure sealants is a new research area and no research has been done till now to compare the retention of conventional Clinpro 3M ESPE and Hydrophilic Ultraseal XT Hydro. Hence, this study was conducted.

After a follow-up period of 6 months, it was seen that 22.72% of the teeth with Clinpro had all the fissures covered with the sealant as compared to Ultraseal XT Hydro which was only 9%. Fifty-nine percent of retention rate was seen with Clinpro compared to Ultraseal XT Hydro sealant (27.27%).

The high rate of retention was seen with Clinpro sealant—75% total retention in a trial conducted by Kumaran<sup>9</sup> and 83% retention in a trial conducted by Rajashekar Reddy et al.<sup>27</sup> One of the reasons could be that it is an unfilled sealant. An unfilled sealant penetrates better into the fissures due to lower viscosity and therefore, is better retained.<sup>28</sup>

Another reason could be its unique property of color change. The original color is pink which changes to white on being cured. The color change indicates that the sealant has been completely cured and also that all the fissures have been sealed with the sealant.<sup>28</sup>

On the other hand, Ultraseal XT Hydro sealant comprises a 58 weight % mixture of inorganic filler particles which reduces

its flow during placement. There is no color change in the sealant after curing. Water sorption by Ultraseal sealant might take place which will subsequently increase solubility and loss of retention.<sup>29</sup> Another reason for failure could be due to the presence of moisture which leads to poor bonding between the hydrophilic sealant and the tooth surface.<sup>29</sup>

According to Beslot-Neveu et al. and Eliades et al., the surface energy of hydrophilic sealants is lower than water because of which they cannot penetrate completely to the bottom of the fissures.<sup>30,31</sup>

A slightly higher incidence of caries was seen with Ultra XT Hydro after 6 months of placement. This could be attributed to the complete loss of Ultra XT Hydro sealant from most of the occlusal surface. No discoloration of sealant was seen at 6 months. Since there was a loss of follow-up of eight study subjects, it could be considered as one of the limitations of the current study. The hydrophilic sealants can be used in public dental health programs and special children due to their reduced sensitivity to moisture.<sup>32</sup>

## CONCLUSION

Based on the findings of the present study, it was concluded that for a longer follow-up period, Clinpro 2M ESPE was better than Ultra XT Hydro seal in terms of retention and cariostatic effect. No difference was observed with regard to the discoloration of the sealants.

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