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3M™ Clinpro™ Sealant

Pit and Fissure Sealant with Color Change Technology

Technical Product Profile

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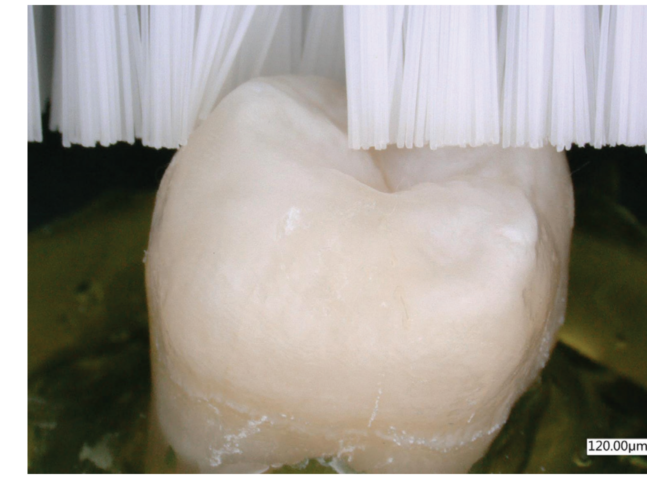
Background

How sealants help protect against caries



Sealants are dental resins that are applied to the pits and fissures of teeth to inhibit dental caries. The success of a sealant depends upon its ability to adhere firmly to the enamel surface, isolating and protecting pits and fissures from the rest of the oral environment. Pits and fissures are fossi and grooves that failed to fuse during development of the tooth. The narrow width and uneven depth make them a haven for debris and acid producing bacteria. Saliva, which helps to clean food particles from other areas of the mouth, cannot clean pits and fissures in molars. Even a single toothbrush bristle is too large to enter and clean most fissures.

The sealant acts as a physical barrier, preventing oral bacteria and dietary carbohydrates from creating the acid conditions that result in caries. Placement of a conventional sealant is a non-invasive technique that maintains tooth integrity while protecting vulnerable pits and fissures from caries attack.

Trapping bacteria beneath sealants is inevitable. Also, it is possible to inadvertently seal over an initial carious lesion. Neither of these processes increase the chance of caries developing or caries growing beneath the surface. The ability of bacteria to survive under a sealant is considerably impaired because carbohydrates cannot reach them. Several investigators have found that the number of bacteria in sealed carious lesions decreases dramatically with time. Radiographs of occlusal lesions that were deliberately sealed for investigational purposes failed to show lesion enlargement several years after being sealed. These findings demonstrate not only that caries will not progress beneath a properly placed sealant, but also that a sealed carious lesion will arrest.[1,2] Nearly 90% of decay in permanent molars occurs on the occlusal surfaces.[3] With the use of pit and fissure sealants, however, occlusal surfaces need not become carious.

How effective are sealants?

The first clinical sealant trial was reported in 1965.[4] Since then, many clinical and laboratory reports have documented sealant safety and effectiveness.[5] The American Dental Association (ADA) first recommended applying sealants in a report published in 1976.[6]

Sealants are primarily used on children, but adults can also benefit from their use.[7] The dental professional must exercise proper patient selection and application techniques. Occlusal sealants are an important preventive strategy especially through the caries-active period. Sealants applied in clinical or school settings prevent about 81% of decay at 2 years after placement and 50% of decay at 4 years after placement.[3]

Important considerations for choosing between unfilled and filled sealants.

The components of sealants are similar to those of composite resin restorative materials to include, methacrylate resins, fillers and modifiers. Sealants are available as filled or unfilled. The addition of filler particles to sealant appears to have little effect on clinical results. Filled and unfilled sealants penetrate the fissures equally well,[8] demonstrate no difference in microleakage,[9] and have similar retention rates.[10,11] Some clinicians feel a filled sealant is better because of a lower wear rate, however the principle behind sealants is to flow down into the pits and fissures to form a barrier. Occlusal wear experienced within a fissure is insignificant and sealant placement should be avoided on the cuspal slopes. The need for occlusal adjustment following sealant placement was studied by Tilliss et al., suggesting that the natural wear of unfilled sealants is sufficient to establish appropriate occlusion, while use of a filled sealant material requires checking the occlusion and possible adjustment of occlusal contacts.[12]

Is it important for a sealant to release fluoride?

Many dental sealants are fluoride releasing. It has been suggested that fluoride release from sealants may have its greatest effect at the base of the sealed groove, providing a fluoride-rich layer that should be more caries resistant, should the sealant be lost. Clinical data comparing fluoride-releasing and non-fluoride-releasing sealants is sparse. In one study, the fluoride-releasing sealant had a slightly higher retention rate after one year than the sealant without fluoride.[13]

How sealant longevity impacts effectiveness.

Sealant effectiveness is directly related to sealant retention since caries will not occur if the sealant remains in place completely covering the pits and fissures. Often dental professionals are reluctant to place sealants because of the fear of loss or partial loss of sealant. The consequences of sealant loss can be diminished with regular maintenance. Retention of sealants can be evaluated through visual and tactile examinations.[14] In the longest clinical study done on sealant retention, the retention rates recorded with 3M™ ESPE™ Concise™ Sealant were 82% at 5 years, 57% at 10 years, and 28% at 15 years.

Seventy-four percent of the sealed permanent first molars were non-carious after 15 years. Researchers only studied a single application of sealant—if the sealants were maintained and reapplied when necessary, the patients could have been caries-free. A single application is not the recommended regimen for placement. The recommendation by the American Dental Association is reapplication every 6 months, if needed.[15]

Sealant Recommendations by Professional Dental Organizations.

In 2016, the American Dental Association and the American Academy of Pediatric Dentistry published evidence-based recommendations to guide clinicians in the prevention of occlusal caries. The evidence showed that sealants are effective for reducing carious lesions in primary and permanent molars.[5]

Applying sealants to sound occlusal surfaces, as well as non-cavitated, carious occlusal surfaces is considered an effective strategy for reducing the incidence of cavitated lesions. In summary the guidance states:

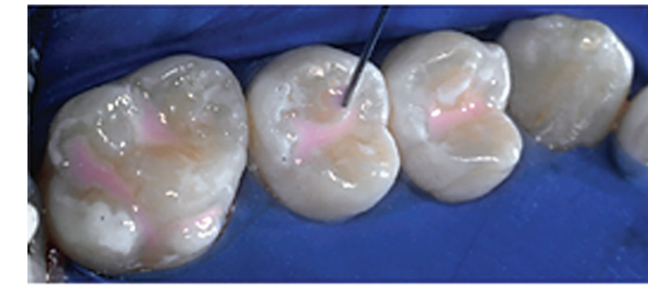
- Sealants are effective in preventing and arresting pit-and-fissure lesions in primary and permanent molars in children and adolescents.
- Sealants can minimize the progression of non-cavitated occlusal carious lesions.
- The panel was unable to recommend one type of sealant material over another.

According to the guidance, "Sealant use should be increased along with other preventative interventions to manage the caries disease process, especially in patients with an elevated risk of developing caries."[5]

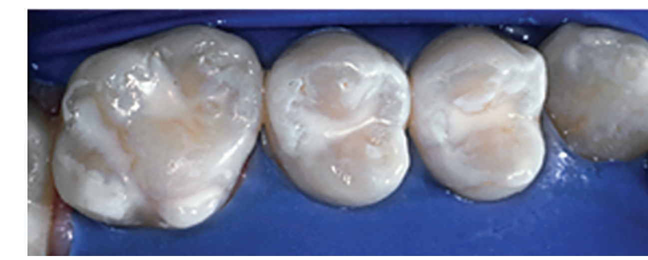
Product Description

3M™ Clinpro™ Sealant is a light-cure, fluoride releasing pit and fissure sealant with a unique color-change feature. Clinpro Sealant is pink when applied to the tooth surface, and changes to an opaque off-white color when exposed to light. The pink color aids the dental professional in the accuracy and amount of material placed during the sealant procedure. When light-cured, the pink sealant will transform to an opaque off-white color. The change of color from pink to opaque off-white is not a cure indicator. The sealant needs to be cured with a dental curing light for the recommended exposure time. A sealant exhibiting any pink coloring is not completely cured.

Clinpro sealant contains a patented soluble organic fluoride source. The fluoride is released from the sealant in a diffusion-limited process by exchange of hydroxide for the fluoride ion. The composition remains homogenous for a prolonged period and allows cured sealant to release fluoride.



Goes on pink



Cures to white

Benefits at a glance:

- Aids in the prevention of caries
- Changes color from pink to white during light cure
- Unfilled: flows into pits and fissures
- Self-occluding: needs little or no adjustment after curing
- Contains fluoride
- Supplied in a syringe or bottle dispenser
- Needle-nose tip on syringe to aid in placement

Clinpro Sealant is packaged in two forms: in 1.2 ml syringes with 27 gauge blunt needle tips for direct delivery to the tooth, and in 6 ml plastic bottles with a drop dispenser tip.

Indications

Clinpro Sealant is designed for sealing the enamel pits and fissures of teeth to aid in the prevention of caries.

Clinpro Sealant meets ISO 6874:2015(E) Dentistry-Polymer-based pit and fissure sealants for a Type II (light-cured) sealant.

Composition

3M™ Clinpro™ Sealant contains two monomers, 2, 2-bis[4-(2-hydroxy-3 methacryloxypropoxy)phenyl] propane and tri(ethylene glycol) dimethacrylate, and a light cure initiator system based on camphorquinone, a tertiary amine, and an iodonium salt. Silane-treated fumed silica (6 wt%) helps provide optimal handling. Titanium dioxide provides the opaque white color. A patented organic fluoride salt provides early and sustained fluoride release. Rose Bengal dye provides the pink coloring which disappears when exposed to a dental curing light.

Application Technique

Dispensing Sealant

Follow the directions corresponding to the dispensing system chosen. Sealant is light sensitive. Exposure to overhead operatory lights will initiate the color change and curing.

Syringe Format

1. Protective eyewear is recommended for patients and staff when using a syringe type dispenser.
2. Prepare delivery system: Remove cap from syringe and SAVE. Twist a disposable tip securely onto the syringe. Holding the tip away from the patient and any dental staff, express a small amount of material onto a mix pad or 2×2 gauze to assure the delivery system is not clogged. If clogged, remove the tip and express a small amount of material from the syringe. Remove any visible plug, if present, from the syringe opening. Replace syringe tip and again check flow from tip. If clog remains, discard dispensing tip and replace with a new one.
3. At the completion of the procedure: Remove used syringe-tip and discard. Twist on storage cap. Storage of the syringe with a used dispensing tip, or without the storage cap, will allow drying or curing of the product and consequent clogging of the system. Replace storage cap with a new dispensing tip at next use.
4. Cleaning and disinfection: Discard used syringe tip. Replace with syringe storage cap. Clean and disinfect the capped syringe as recommended by the guidance by the Centers for Disease Control and P*revention. Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care.* Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human Services; October 2016. https://www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-care2.pdf[16] Follow disinfectant manufacturer's instructions for wet contact time.

Bottle Format

1. Dispense 1 to 2 drops of sealant into the mix well. Immediately slide cover over well to protect from light.
2. Re-cap sealant bottle.
3. After removing material from mix well, always replace cover slide.
4. Cleaning and disinfection: Clean and disinfect the bottle, mix well and applicator handles—following the guidance for non-critical, non-patient contacting devices by the Centers for Disease Control and Prevention. *Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care*. Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human Services; October 2016. https://www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-care2.pdf [16] Follow the disinfectant manufacturer's instructions for wet contact time.

Select teeth:

Teeth must be sufficiently erupted so that a dry field can be maintained.

- Clean Enamel. Thoroughly clean teeth to remove plaque and debris from enamel surfaces and fissures. Rinse thoroughly with water. Note: Do not use any cleaning medium that may contain oils.
- Isolate teeth and dry. While a rubber dam provides the best isolation, cotton rolls used in conjunction with isolation shields, are acceptable.

Etch Enamel:

- Using syringe tip, or fiber tip, apply a generous amount of etchant to all enamel surfaces to be sealed, extending beyond the anticipated margin of the sealant.
- Etch for a minimum of 15 seconds, but no longer than 60 seconds.

Rinse Etched Enamel:

- Thoroughly rinse teeth with air/water spray to remove etchant.
- Do not allow patient to swallow or rinse. If saliva contacts the etched surfaces, re-etch for 5 seconds and rinse.

Dry Etched Enamel:

- Thoroughly dry the etched surfaces.
- Air should be oil and water free.
- The dry etched surfaces should appear as a matte, frosty white. If not, repeat steps 1 and 2. Do not allow the etched surface to be contaminated.

Apply Sealant:

- Using the syringe needle tip or a brush, apply sealant into the pits and fissures. Do not let sealant flow beyond the etched surfaces.
- Stirring the sealant with the syringe-tip during or after placement will help eliminate any possible bubbles, and enhance the flow into the pit and fissures. An explorer may also be used.

Light-Cure:

- Cure the sealant by exposing it to light from a 3M™ Curing Light, or other curing unit of comparable intensity.
- See light curing guide below to select curing time. The tip of the light should be held as close as possible to the sealant, without actually touching the sealant. When set, the sealant forms a hard, opaque film, light yellow in color with a slight surface inhibition.

Wipe Clean:

- Wipe the sealant with a cotton applicator to remove the thin film on the surface.

As an alternative to the acid-etch technique, the use of 3M™ Adper™ Prompt™ Self-Etch Adhesive or 3M™ Scotchbond™ Universal Adhesive may be substituted. Follow the Adper Prompt adhesive or Scotchbond Universal adhesive instructions, sections titled: Instructions for bonding light-cured dental sealants. If Adper Prompt adhesive or Scotchbond Universal adhesive is used, enamel must still be thoroughly cleaned and isolated; follow instructions 1-4 in the acid-etch technique.

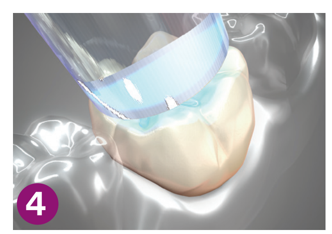
Pit and Fissure Sealant application technique

Apply etchant to all enamel surfaces to be sealed.

Note: Adhesive may be used instead of etch technique.

Thoroughly rinse teeth to remove etchant, then dry the etched surfaces.

Apply 3M™ Clinpro™ Sealant into pits and fissures.



Light cure the sealant according to manufacturer's instructions.
LED: 10 sec.
Halogen: 20 sec.

All halogen lights (with output of 550-1000 mW/cm^2)	All LED lights (with output 1000-2000 mW/cm^2)
20 seconds	10 seconds

In Vitro Studies

Shear Bond Strength

Shear bond strength to uncut bovine enamel was tested using three bonding methods (n=5): (a) etch for 15 seconds with 3M™ Scotchbond™ Universal Etchant, (b) primed with 3M™ Scotchbond™ Universal Adhesive, without etching, and (c) primed with 3M™ Adper™ Prompt™ L-Pop™ Adhesive, without etching. Samples were stored overnight at 36°C before testing. The resulting data in Figure 1 show that 3M™ Clinpro™ Sealant can attain strong bond with acid etching, Adper Prompt adhesive, or Scotchbond Universal adhesive.

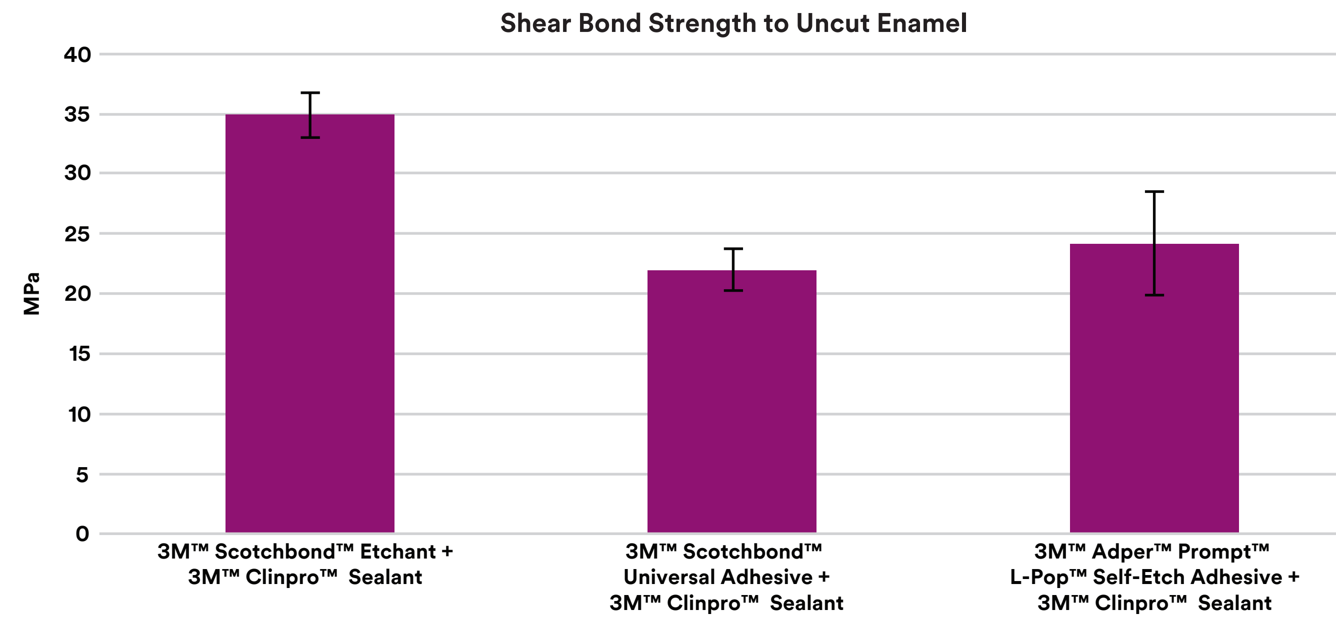


Figure 1: 24 hr shear bond strength of Clinpro Sealant to uncut enamel used with Scotchbond Universal Etchant, Scotchbond Universal Adhesive, or Adper Prompt L-Pop Adhesive. *Source: 3M internal data*

Microtensile Bond Strength

Figure 2 shows microtensile bond strength (mTBS) of sealants bonded to buccal enamel surfaces of bovine teeth. 3M™ Clinpro™ Sealant was applied with either etching or 3M™ Adper™ Prompt™ L-Pop™ Self-Etch Adhesive; the other sealants were applied with etching (n=11-14). The mTBS of Clinpro Sealant with Adper Prompt adhesive was statistically not different from Ultraseal XT® hydro and Grandio Seal, and was statistically greater than Clinpro Sealant with etch, Helioseal® F, Helioseal® Clear, and Embrace® WetBond®. The mTBS of Clinpro Sealant with etch was statistically greater than Embrace WetBond, and statistically not different from Ultraseal XT and Grandio Seal, Helioseal F, and Helioseal Clear.

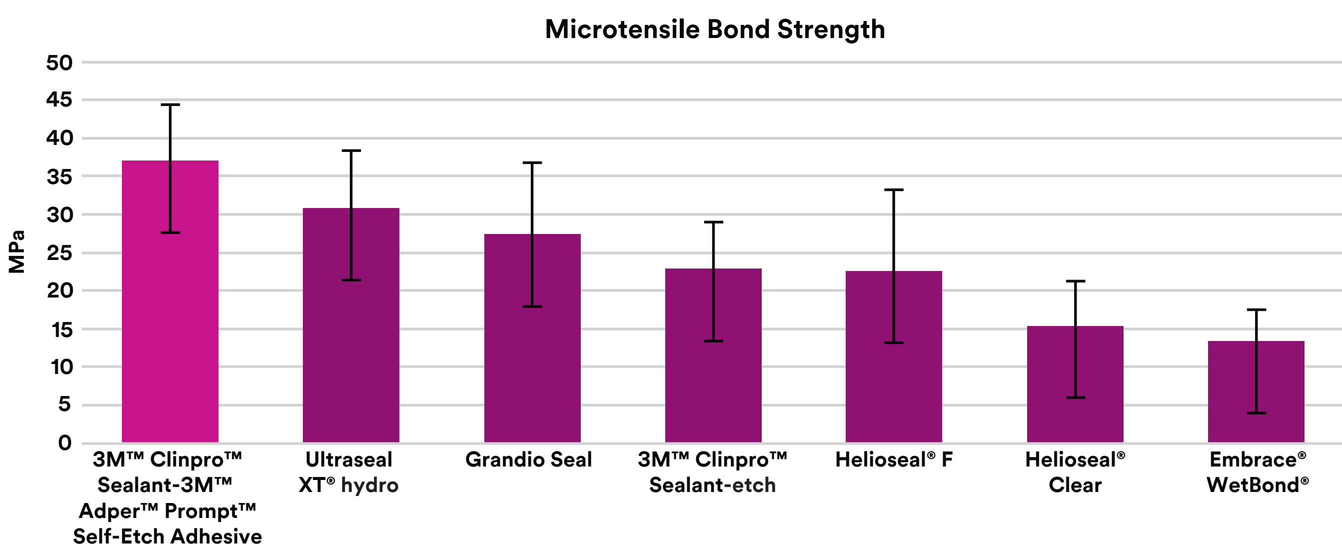


Figure 2: Microtensile bond strength of sealants bonded to buccal enamel surfaces of bovine teeth. *Source: 3M internal data*

Figure 3 shows microtensile bond strength of sealants bonded to buccal enamel surfaces of bovine teeth measured by Papacchini et al. [2006].[17] Clinpro Sealant and Delton® Sealant were applied with etching, Dyract® Seal was applied with a non-rinse conditioner, and Fuji II LC with GC Cavity Conditioner.

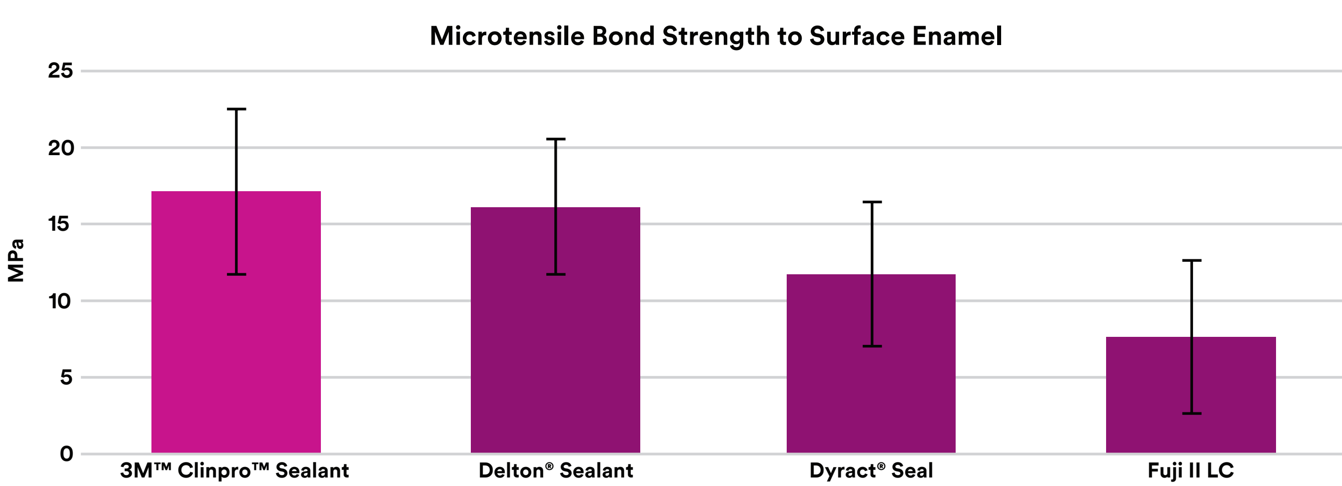


Figure 3: Microtensile bond strength of sealants bonded to buccal enamel surfaces of bovine teeth. *Source: Papacchini et al., 2006*

Microleakage

In a study by Rirattanapong et al. (2017)[18], sealants were applied to extracted human molars. After phosphoric acid etching: for each sealant, half were applied without contamination, and half were contaminated with saliva for 20 seconds, then dried. After thermocycling, microleakage from methylene blue dye immersion was measured. 3M™ Clinpro™ Sealant demonstrated superior resistance to microleakage compared to Fuji VII under both non-contaminated and saliva-contaminated application.

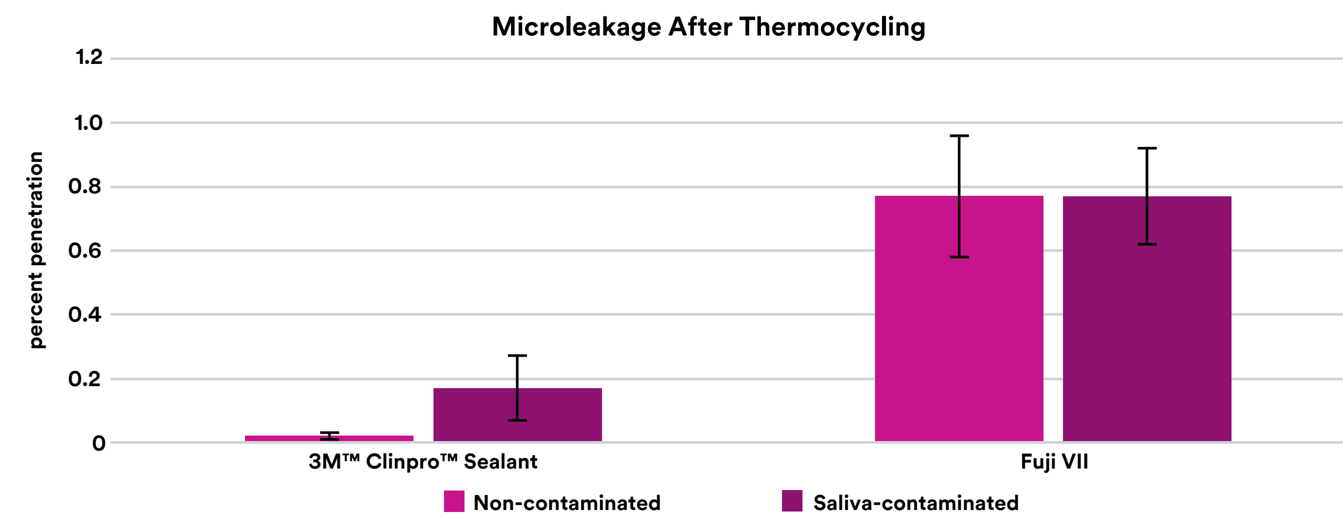


Figure 5: Microleakage after thermocycling. *Source: Rirattanapong et al., 2017.*

Rodriguez et al. (2011)[19] studied microleakage of sealants on extracted human molars after mechanical loading and thermocycling. The percentage of continuous margin was measured under a scanning electron microscope; microleakage was measured after immersion in cresyl blue dye. Figure 6 shows microleakage after thermal-mechanical loading. Clinpro Sealant was statistically not different from Optibond™ FL and Delton® LC, and statistically lower than Grandio Seal, Embrace™ WetBond™, and Seal-N-Glo.® Figure 7 shows marginal adaptation after thermal-mechanical loading. Clinpro Sealant was equivalent to Optibond FL, Delton LC, and Seal-N-Glo, and higher than Grandio Seal and Embrace WetBond.

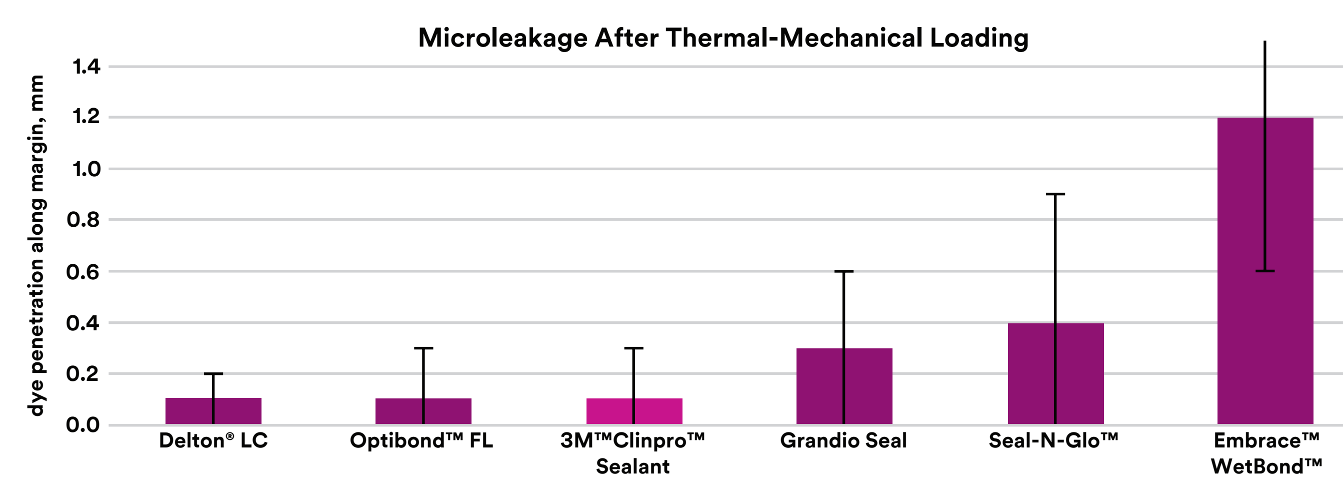


Figure 6: Microleakage after thermal-mechanical loading. *Source: Rodriguez et al., 2011.*

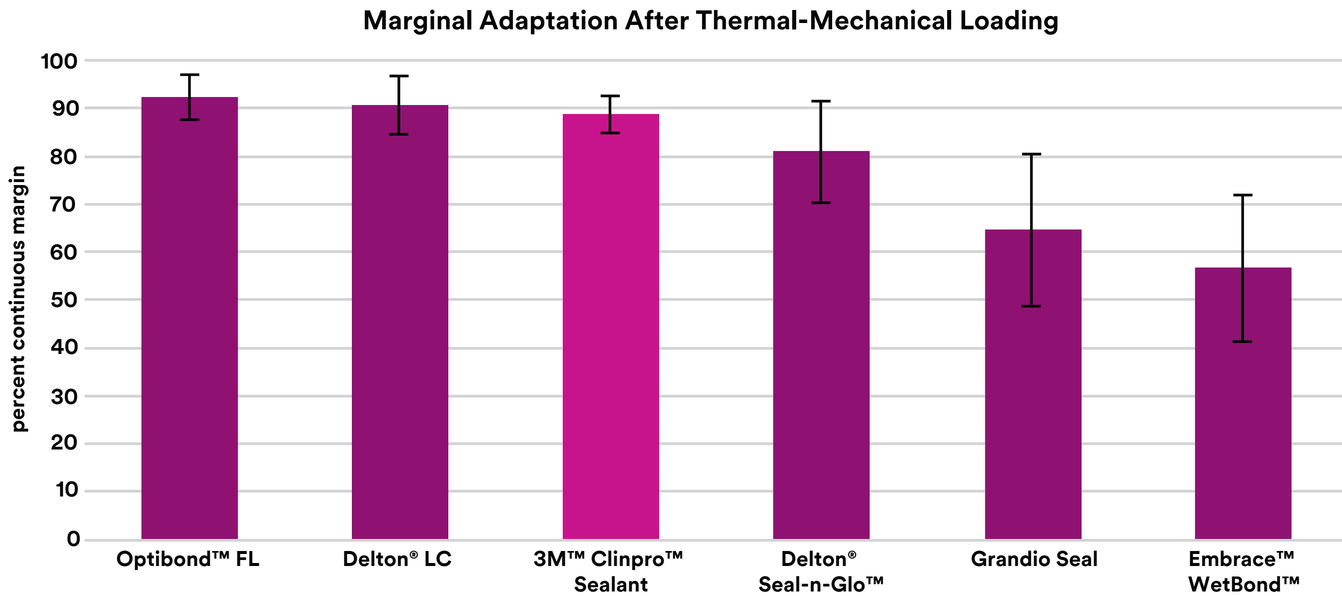


Figure 7: Marginal adaptation after thermal-mechanical loading. *Source: Rodriguez et al., 2011*

Retention after Chewing Simulation

In a study by Fok et al. (2011),[20] sealants were placed on extracted human molars with three techniques and subjected to 300,000 cycles of chewing with a human molar antagonist and a birdseed slurry, simulating approximately one year of chewing activity. Sealants with all three placement techniques remained intact. The investigators noted no difference in performance among the three techniques. Figure 8 shows representative photos of the samples.

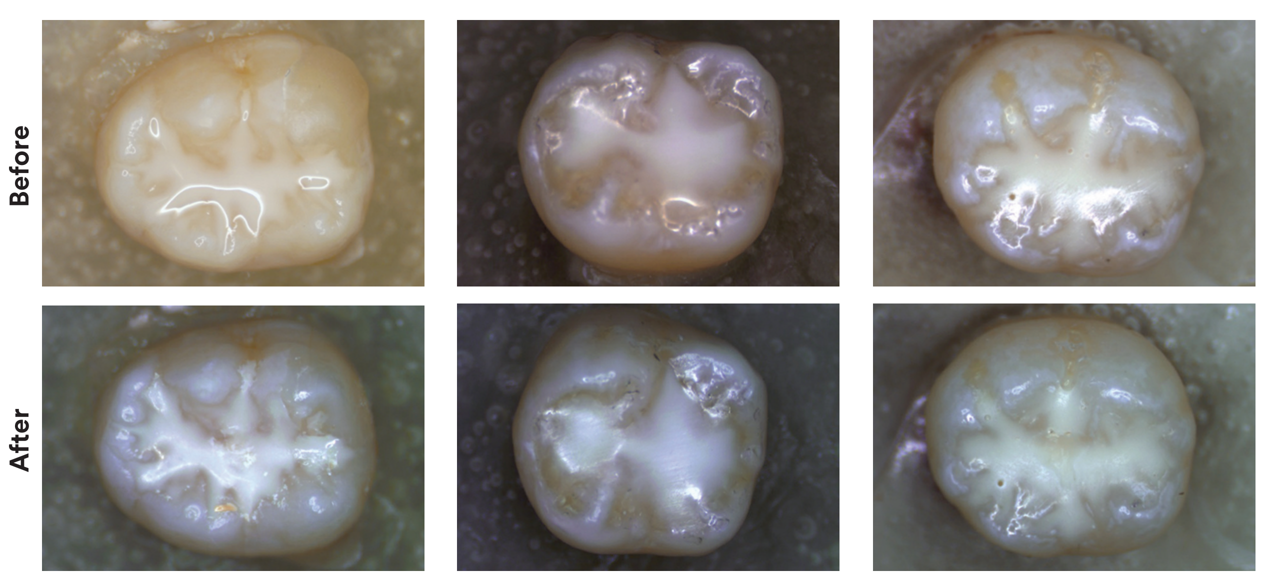


Figure 8: Retention of 3M™ Clinpro™ Sealant after chewing simulation.

Microgap Infiltration

Infiltration depth was measured on sealants applied to standardized gaps formed by glass slides separated by shims of 33 or 77 micrometers, to simulate fissures in a molar (n=6). 3M™ Clinpro™ Sealant exhibited statistically greater microgap infiltration depth than Ultraseal XT® plus, Ultraseal XT® hydro, Embrace™ WetBond™, Delton® FS, Helioseal® F, BioCoat™, BeautiSealant; and, was statistically not different from Grandio Seal.

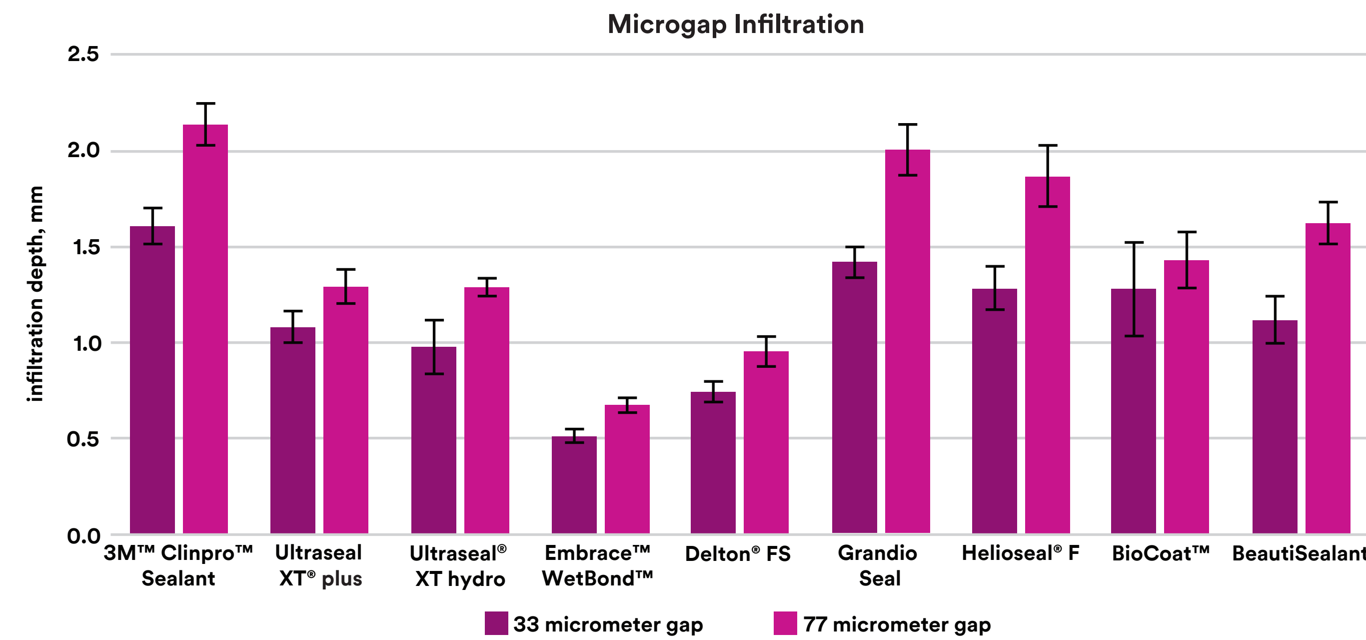


Figure 10: Infiltration depth into 33 and 77 micrometer microgaps. *Source: 3M internal data*

Fluoride Release

Cured disks of sealant (1 mm thick, 20 mm diameter) were stored in deionized water at 37°C; the water was exchanged periodically and fluoride concentration measured with a fluoride ion electrode (n=3). 3M™ Clinpro™ Sealant had greater cumulative fluoride release than Ultraseal XT® plus Pit and Fissure Sealant and Helioseal® F after 28 days.

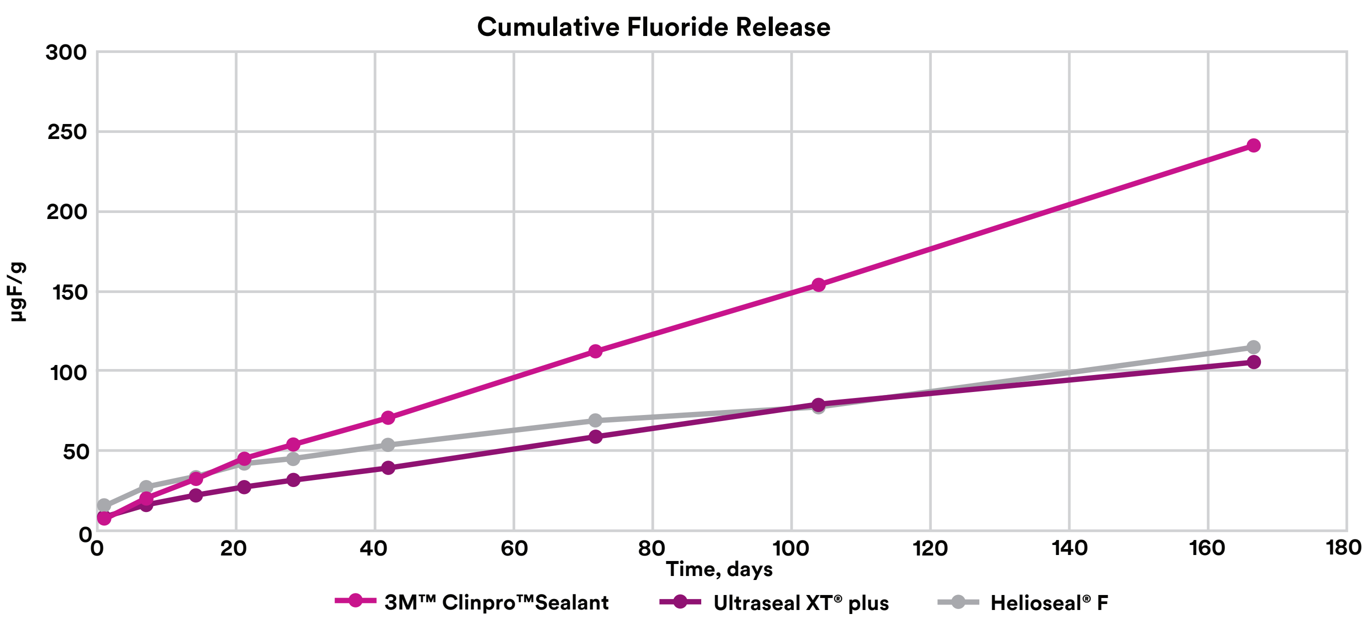


Figure 11: Fluoride release from sealants. *Source: 3M internal data*

Fluoride Recharge

The fluoride release of 3M™ Clinpro™ Sealant was measured before and after multiple treatments with 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste, 3M™ Clinpro™ Tooth Crème 0.21% Sodium Anti-Cavity Toothpaste, and after a single treatment of 3M™ Vanish™ 5% Sodium Fluoride White Varnish. Treatment with Clinpro 5000 toothpaste or Clinpro Tooth Crème resulted in enhanced fluoride release from Clinpro Sealant up to six hours afterward; this recharge effect is repeatable. Treatment with Vanish White Varnish also resulted in enhanced fluoride release up to six hours later. This demonstrates that Clinpro Sealant can absorb and re-release fluoride from a variety of topical fluoride treatments.

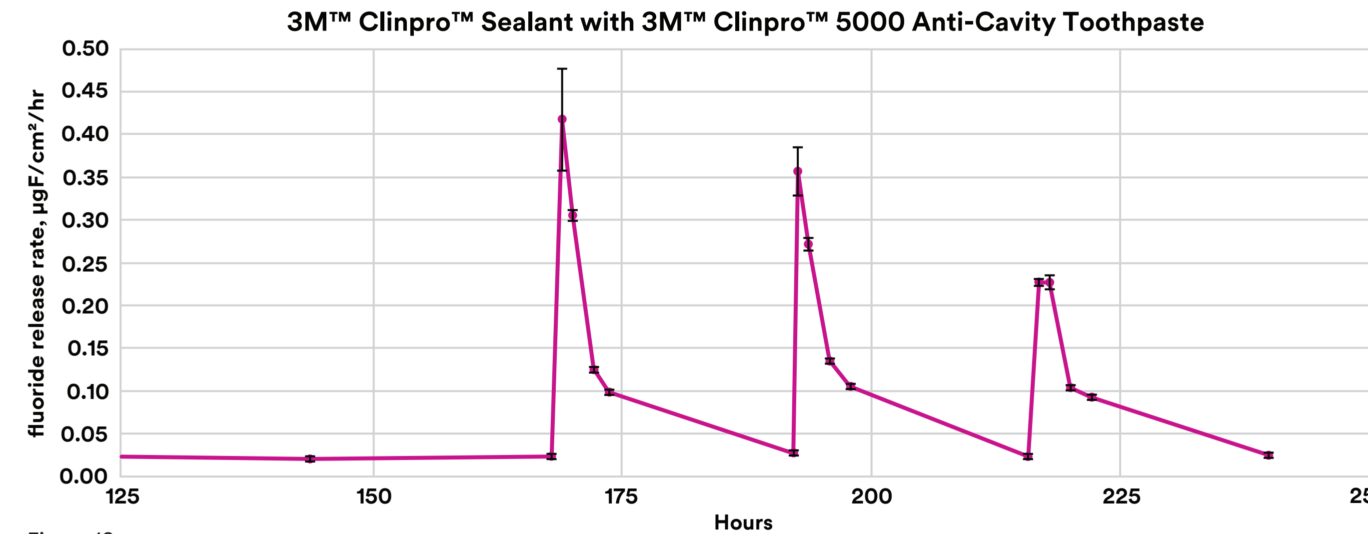


Figure 12.

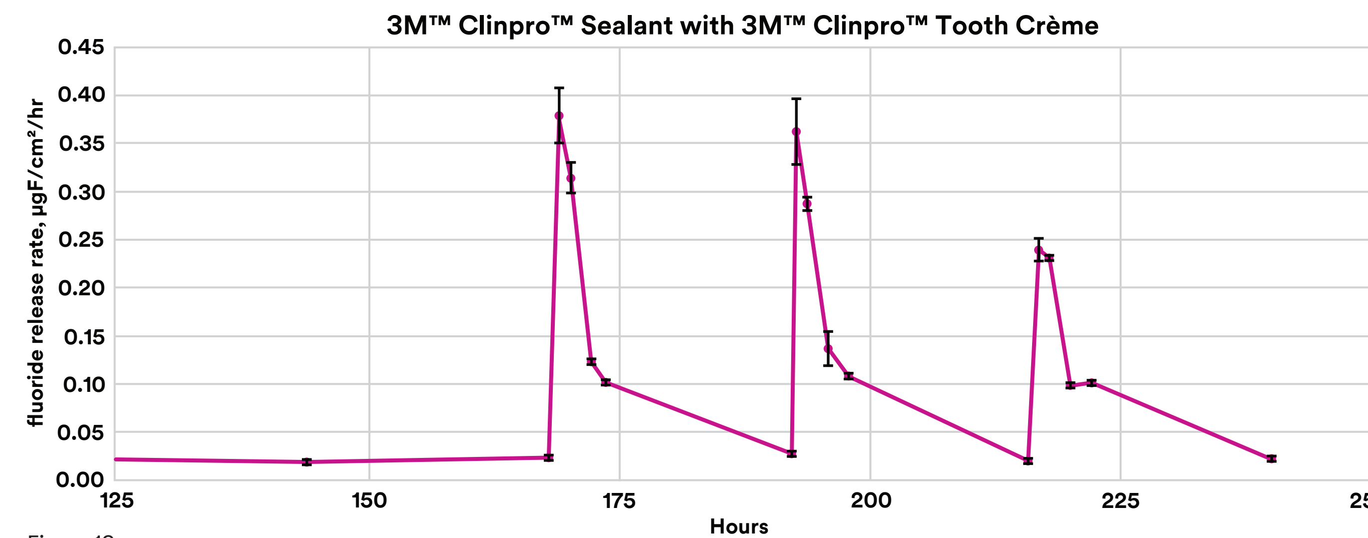


Figure 13.

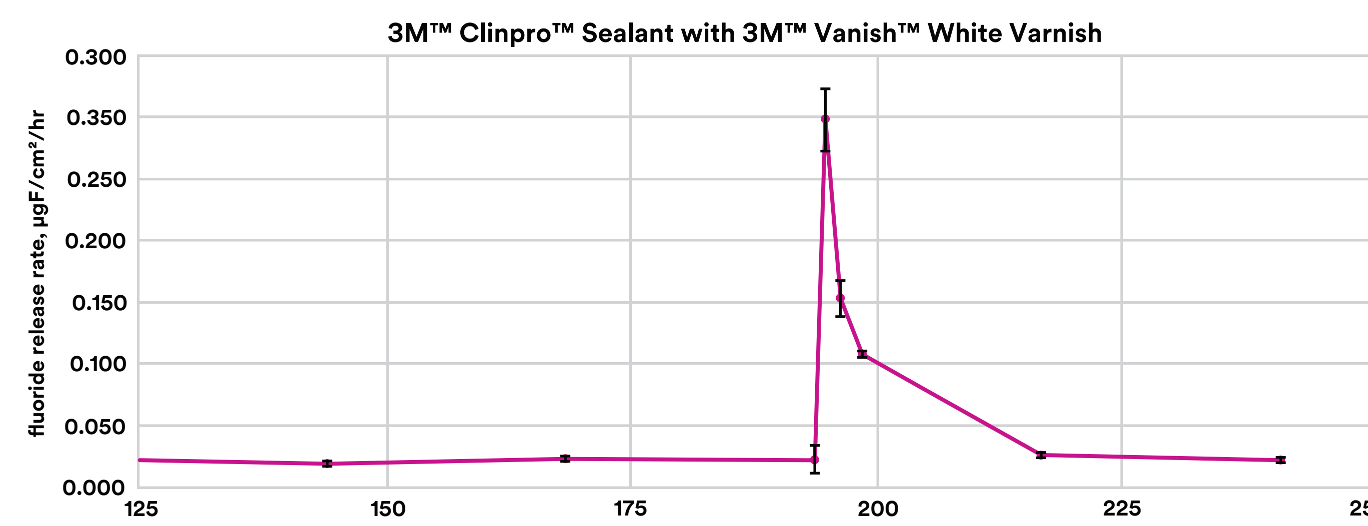


Figure 14.

Figures 12, 13 and 14: Fluoride release rate of Clinpro Sealant after treatments of (12) Clinpro 5000 Toothpaste; (13) Clinpro Tooth Crème; (14) Vanish Varnish.

Enamel Fluoride Uptake

In an in vitro study, polished bovine enamel was demineralized using a solution of 0.1 M lactic acid and 0.2% carbopol. A 2mm band of sealant was applied on the acrylic around the perimeter of the enamel, taking care not to touch the enamel with sealant (n=6). The samples were immersed in 37°C deionized water for three months; fluoride concentration in the enamel was measured periodically via microdrill biopsy. The enamel fluoride uptake (EFU) of 3M™ Clinpro™ Sealant was statistically significantly higher than Biocoat™ Bioactive Resin Pit and Fissure Sealant, Ultraseal XT® plus Pit and Fissure Sealant, and the untreated control at one week through three months. BioCoat and Ultraseal XT plus were statistically not different from the untreated control at all time points, except at the 2 week time point when Ultraseal XT plus was lower.

In a second study using the same method, the enamel fluoride uptake of Clinpro Sealant at two months was statistically significantly higher than Ultraseal XT® hydro, Grandio Seal, Helioseal® F, and the untreated control; Ultraseal XT hydro and Grandio Seal, were statistically not different from the untreated control at all time points.

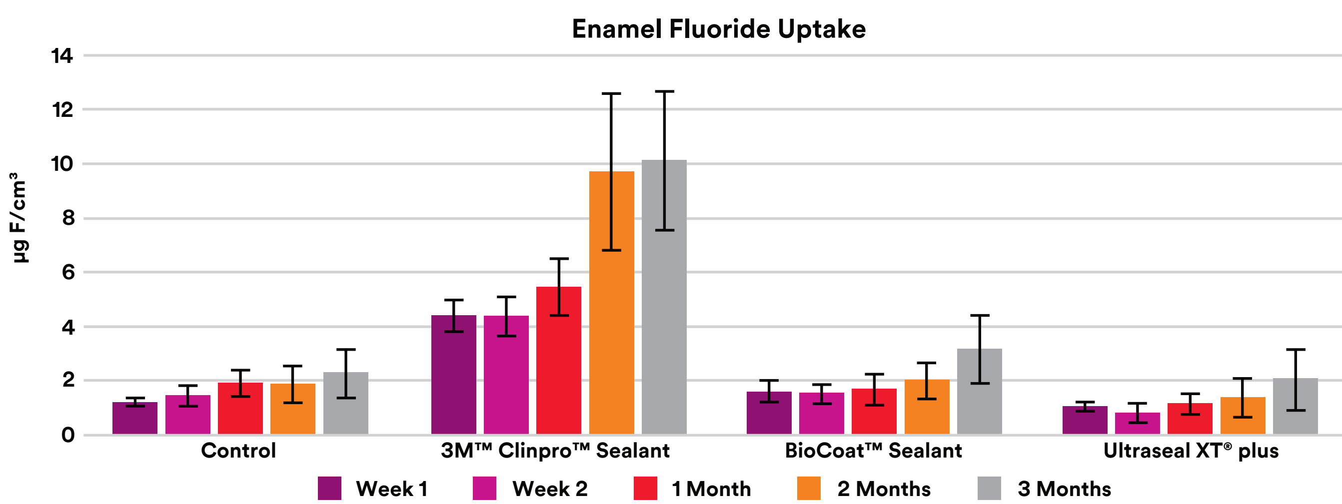


Figure 15: Enamel fluoride uptake through three months. *Source: 3M internal data*

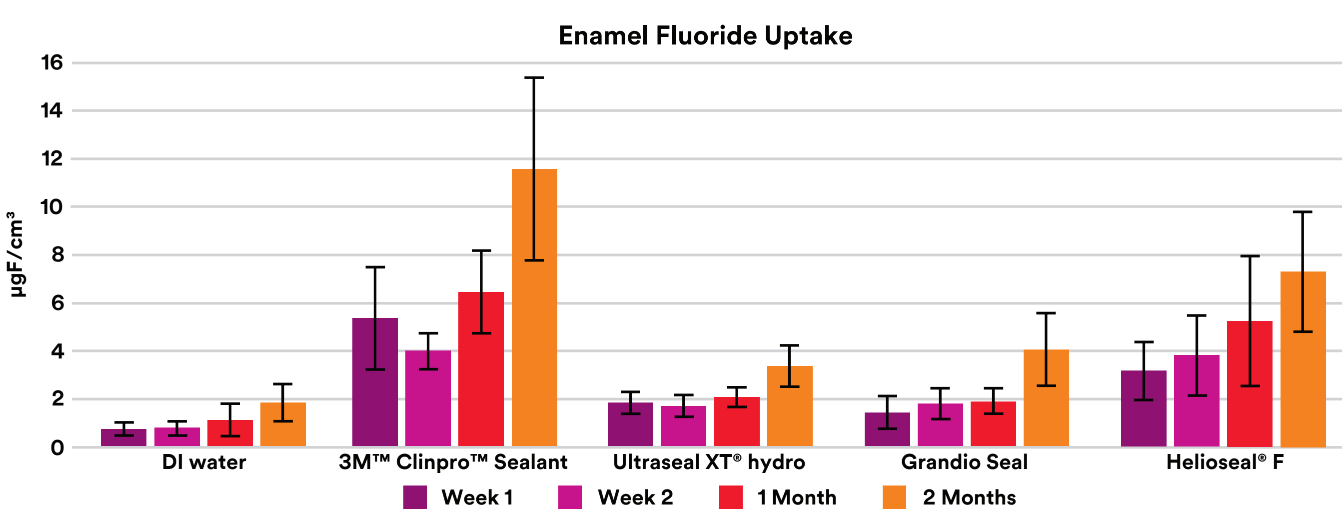


Figure 16: Enamel fluoride uptake through two months. *Source: 3M internal data*

Adjacent Enamel Protection

In a study by Ei et al. (2017),[21] shallow troughs prepared on bovine enamel blocks filled with sealant were incubated in artificial saliva for 14 days, then immersed in an acetic acid challenge (pH=4.8) for 10 days. Nanohardness measurements were taken in an array from 0-200 µm from the sealant edge and 0-200 µm from the enamel surface. This measures the remaining mineral content within that volume. The mineral content in the uncoated adjacent enamel of 3M™ Clinpro™ Sealant was statistically higher than the flowable composite control (Estelite® Flow Quick), and statistically not different from a glass ionomer sealant (Fuji VII). Clinpro Sealant reduced demineralization of uncoated enamel up to 200 µm away.

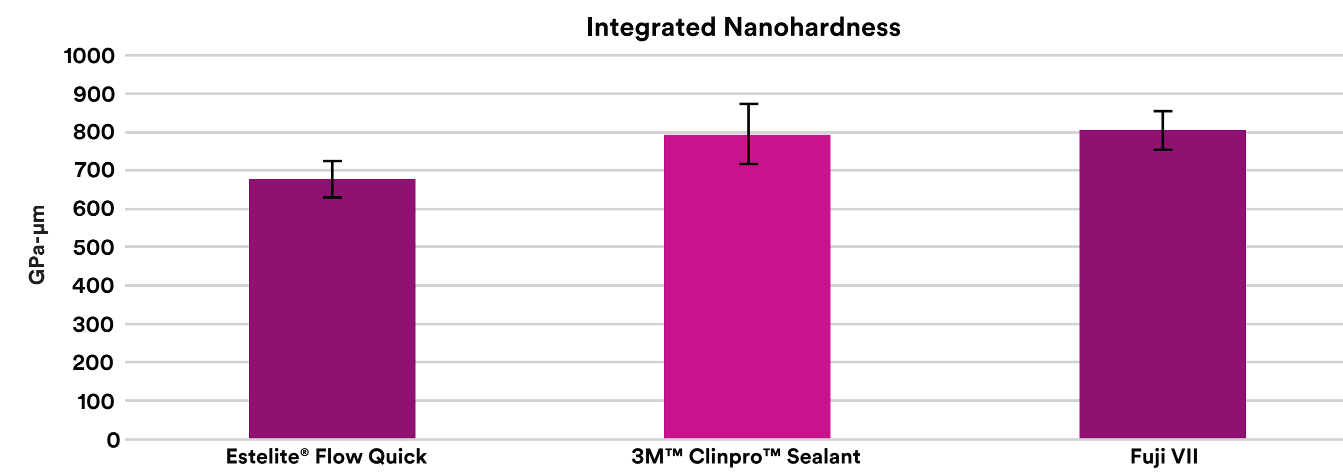


Figure 17: Integrated nanohardness of uncoated enamel 200 micrometers from the sealant edge. Higher values mean higher mineral content (less mineral loss). *Source: Ei et al, 2017.*

In a study by Alsaffar et al. (2011),[22] extracted human teeth with sealants applied underwent a 20-day lactic acid challenge; mineral loss (ΔZ) profiles of uncoated enamel 0.5mm from the sealant were calculated from transverse microhardness data. The mineral loss for Clinpro Sealant was statistically lower than Delton® Opaque and Ultraseal XT® plus. Clinpro Sealant reduced demineralization of uncoated enamel up to 0.5 mm away.

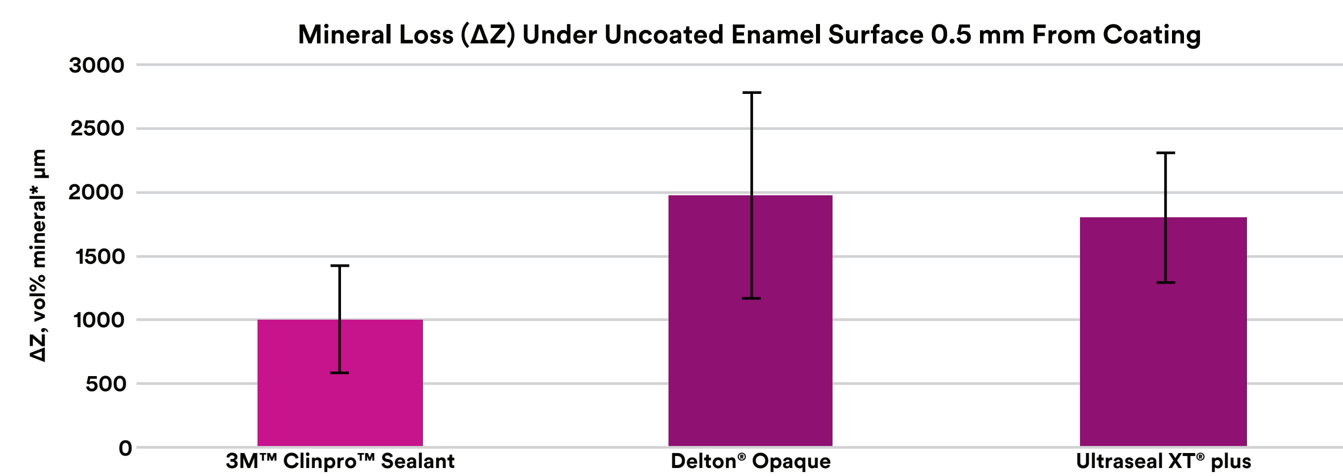


Figure 18: Mineral loss (ΔZ) under uncoated enamel surface 0.5 mm from sealant edge. *Source: Alsaffar et al., 2011*

Plaque Resistance

Disks of bovine enamel and 3M™ Clinpro™ Sealant were inoculated with whole human saliva from a volunteer, then immersed in growth medium for 26 hours (n=4). All specimens were sterilized with ethanol prior to incubation. Plaque was collected to determine plaque biomass and lactic acid concentration after a sucrose challenge. These parameters were used to signify caries activity and were measured by colorimetry. The plaque accumulation on Clinpro Sealant was statistically not different from natural enamel. Lactic acid release with sucrose challenge from plaque biofilm on Clinpro Sealant was statistically significantly lower than for natural enamel.

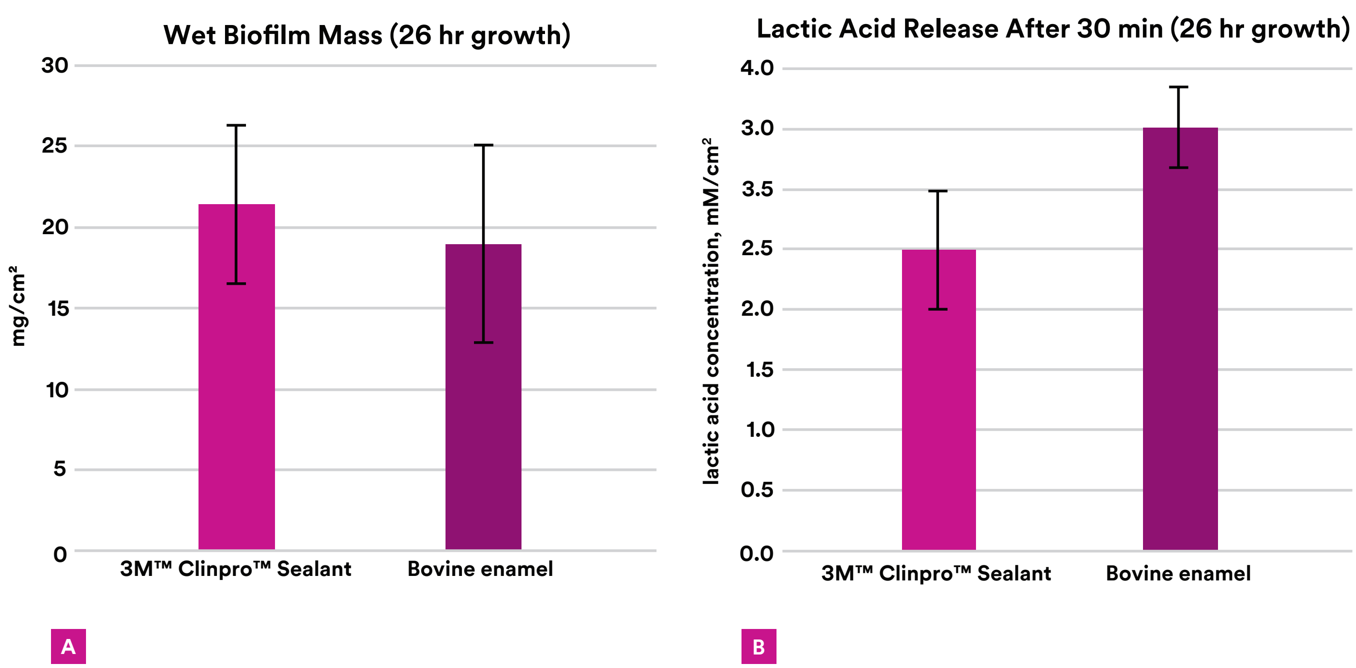
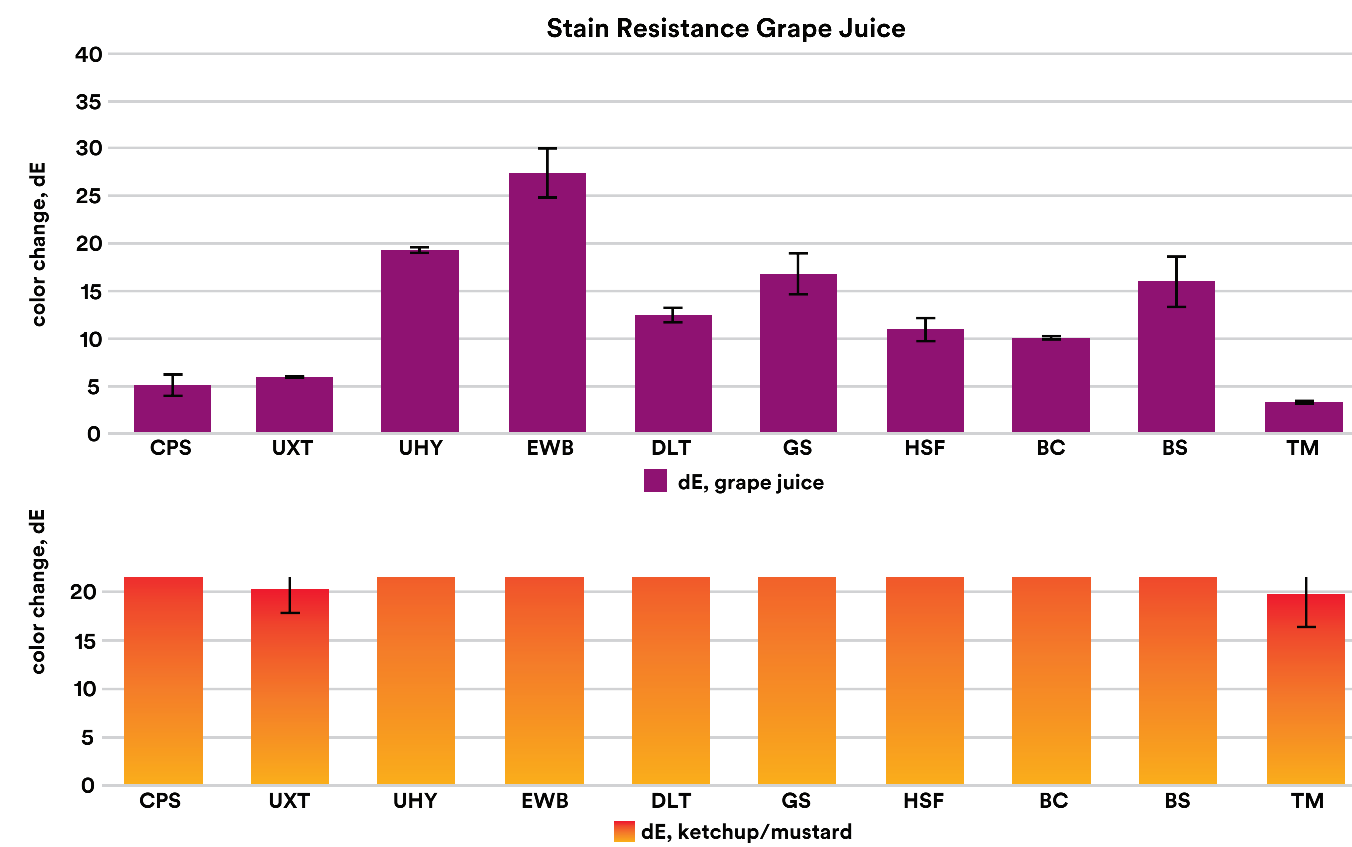


Figure 19: Plaque results. (a) wet biofilm mass; (b) lactic acid concentration after sucrose challenge. *Source: 3M internal data*

Stain Resistance

One millimeter thick disks of sealant materials were immersed at 37°C in either grape juice for 3 days, or a mixture of ketchup and mustard for 4 hours (n=3). Color was measured on a spectrophotometer before and after immersion. 3M™ Clinpro™ Sealant resists ketchup and mustard staining better than Embrace™ Wetbond™, Helioseal® F, BioCoat™, Delton®, Ultraseal XT® hydro, and Grandio Seal. Clinpro Sealant resists grape juice staining better than Embrace Wetbond, Helioseal F, BioCoat, Delton, BeautiSealant, Ultraseal XT Hydro, and Grandio Seal.



Legend:

CPS = 3M™ Clinpro™ Sealant
UXT = Ultraseal XT® plus Pit and Fissure Sealant
UHY = Ultraseal XT® hydro™ Pit and Fissure Sealant
EWB = Embrace™ WetBond™ Pit & Fissure Sealant
DLT = Delton® FS+ Flowable Pit and Fissure Sealant
GS = Grandio Seal Pit and Fissure Sealant
HSF = Helioseal® F Fissure Sealant
BC = BioCoat™ Bioactive Resin Pit & Fissure Sealant
BS = BeautiSealant™ Fluoride Releasing Pit & Fissure Sealant System
TM = Teethmate™ F-1 Light Cured Pit & Fissure Sealant

Figure 20: Color change after grape juice (top) and ketchup/mustard (bottom) stain challenges. Lower values mean less staining.
Source: 3M internal data

Three-Body Wear

The 3-body wear of 3M™ Clinpro™ Sealant, Embrace™ WetBond™, and Teethmate™ F-1 was determined with an ACTA Wear Machine (ACTA, Amsterdam, NL). The material loss in micrometers (µm) was measured after 200,000 cycles with a profilometer (n=2). The wear of Clinpro Sealant was statistically not different from Embrace WetBond and Teethmate.

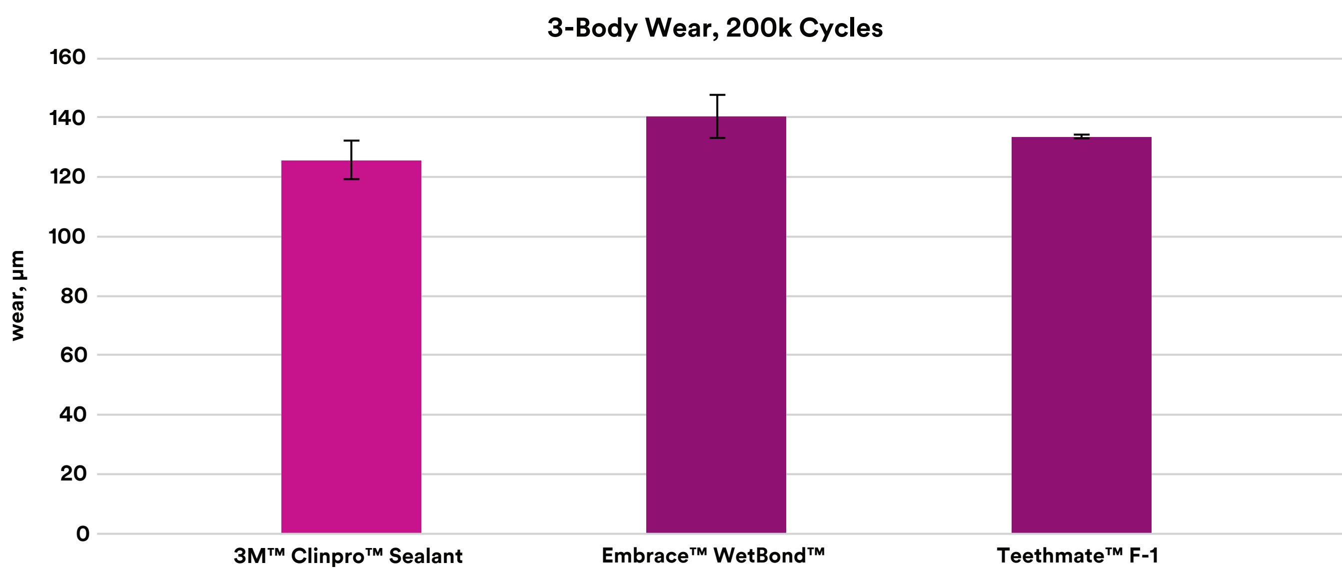


Figure 21: 3-body wear. *Source: 3M internal data*

In Vivo Evaluations and Studies

Clinical Application Evaluation

3M™ Clinpro™ Sealant was evaluated in vivo with 148 practicing dentists, hygienists, and assistants in the United States and throughout the world. The respondents within the U.S. were equally divided between the three professions and used a variety of sealant products. Eighty-three percent of the evaluators found the placement of Clinpro Sealant to be easier because of the color change feature.

Evaluators rated six different characteristics from 1 to 5 (1 = poor and 5 = excellent). A majority of the evaluators rated Clinpro Sealant as a 4 or 5 on all six features shown in Figure 22.

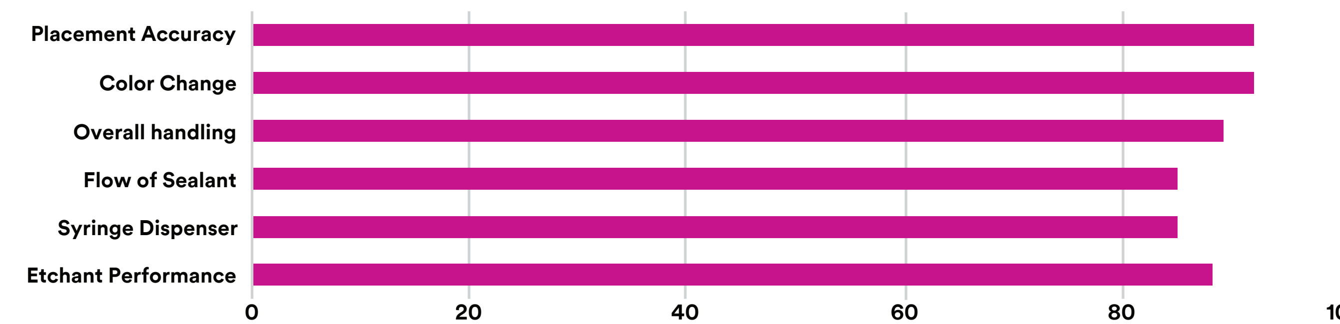


Figure 22: Percentage of 4 and 5 ratings for Clinpro Sealant. *Source: 3M internal data*

A high percentage (88%) said they experienced the same or fewer bubbles with Clinpro Sealant compared to their current product.

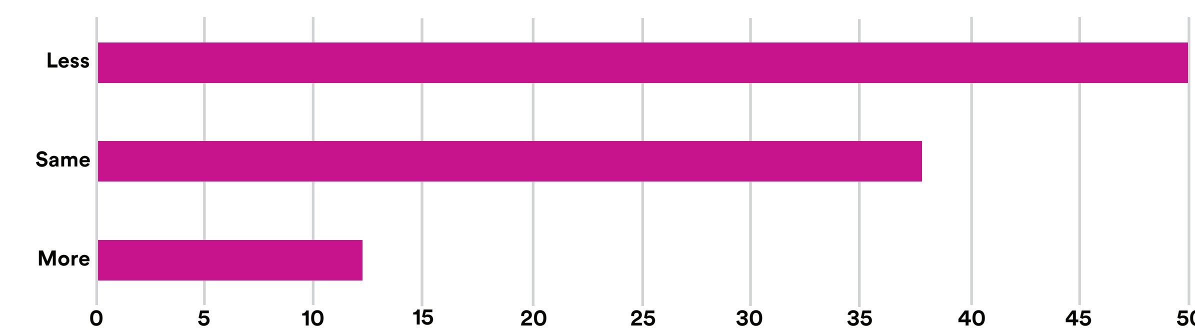


Figure 23: Percentage of respondents reporting bubbles with Clinpro Sealant compared to their current sealant product. *Source: 3M internal data*

Over three-quarters (77%) rated the overall performance of Clinpro Sealant to be better than the sealant product they currently used.

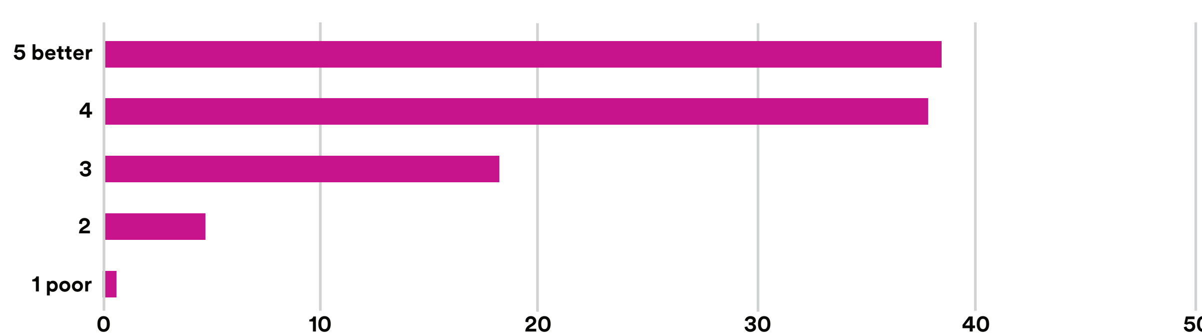


Figure 24: Clinpro Sealant performance compared to current sealant product. *Source: 3M internal data*

Longitudinal Clinical Studies

In a study by Zhang et al. (2017),[23] the retention rate of sealants placed on 405 eight-year-old children in Wuhan, China, in a block-randomised design, were assessed through four years. The cumulative survival rate after 4 years of 3M™ Clinpro™ Sealant on occlusal surfaces was statistically significantly higher than a high viscosity glass ionomer and a glass carbomer (Figure 25). Clinpro Sealant exhibited a cumulative survival rate of 81% after four years. In further analysis of the study data (Goldman et al, 2016),[24] the cumulative survival of cavitated dentin carious lesion-free pits and fissures with Clinpro Sealant was 99% at 2 years and 96% at 4 years.

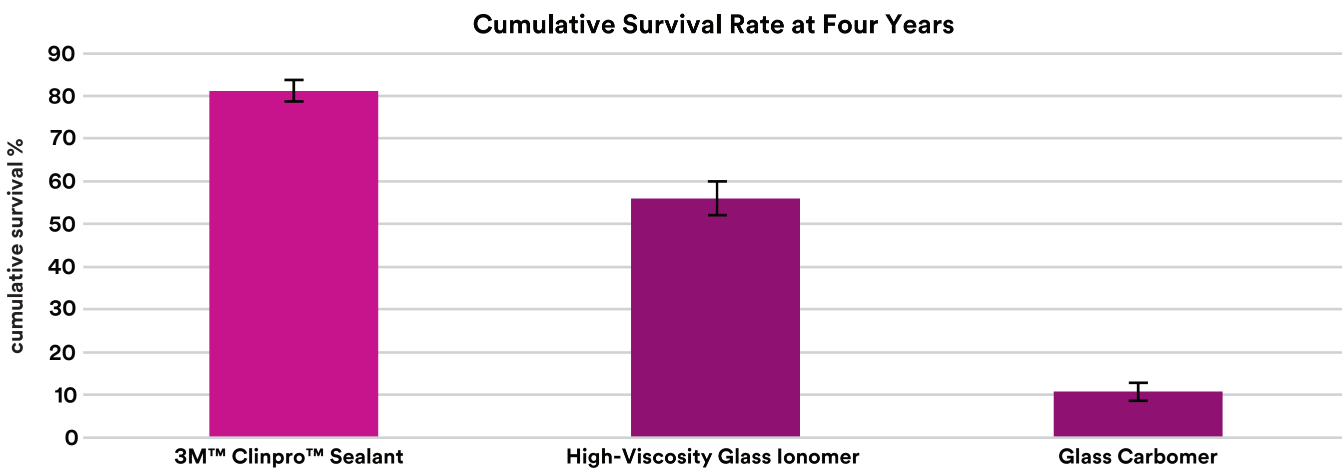


Figure 25: Cumulative survival rate after four years. *Source: Zhang et al., 2017*

In a study by Liu et al. (2012),[25] 501 children (9.1 year average) in Guangzhou, China, received one of four treatments on their molar teeth (1,539 molars): Clinpro Sealant, annual silver diamine fluoride (SDF) application, biannual sodium fluoride varnish application, or placebo control. Examinations were conducted every 6 months through 24 months by a masked examiner. Fissures in all three treatment groups provided statistically significantly lower risk of dentin caries development than the untreated control.

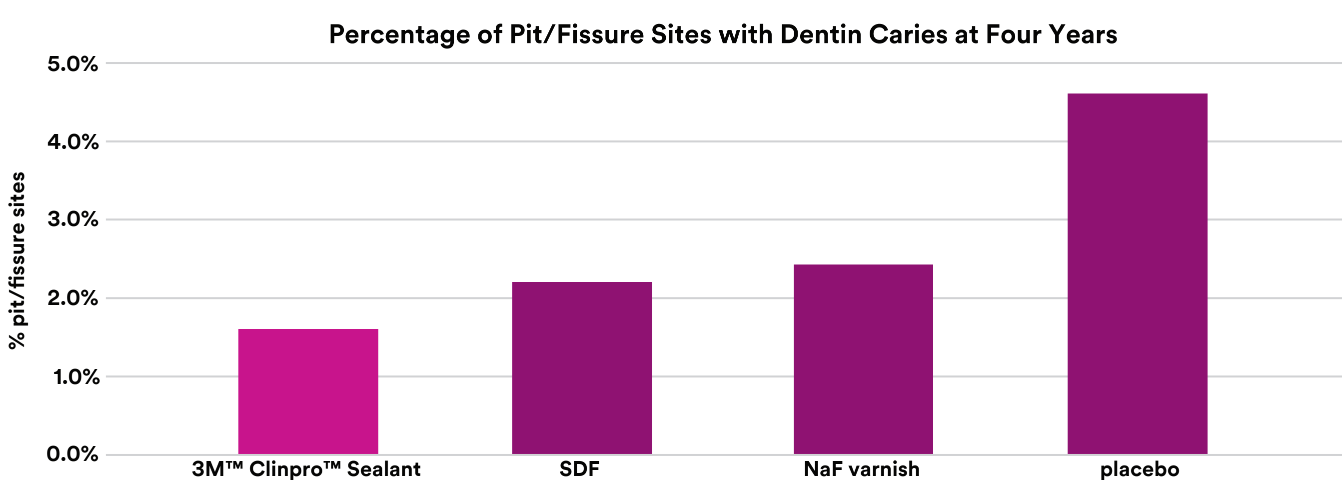


Figure 26: Percent of pit/fissure sites with dentin caries. *Source: Liu et al., 2012*

In a split-mouth, randomized clinical trial by Al-Jobair et al. (2017),[26] 140 fully erupted permanent first molars in children aged 6-9 years, in Riyadh, Saudi Arabia, were sealed with either 3M™ Clinpro™ Sealant or a glass ionomer. Retention and caries status were evaluated semi-annually through 18 months. The cumulative survival percentage of sealant retention and caries-free pits and fissures were statistically not different for Clinpro Sealant and the glass ionomer at 18 months.

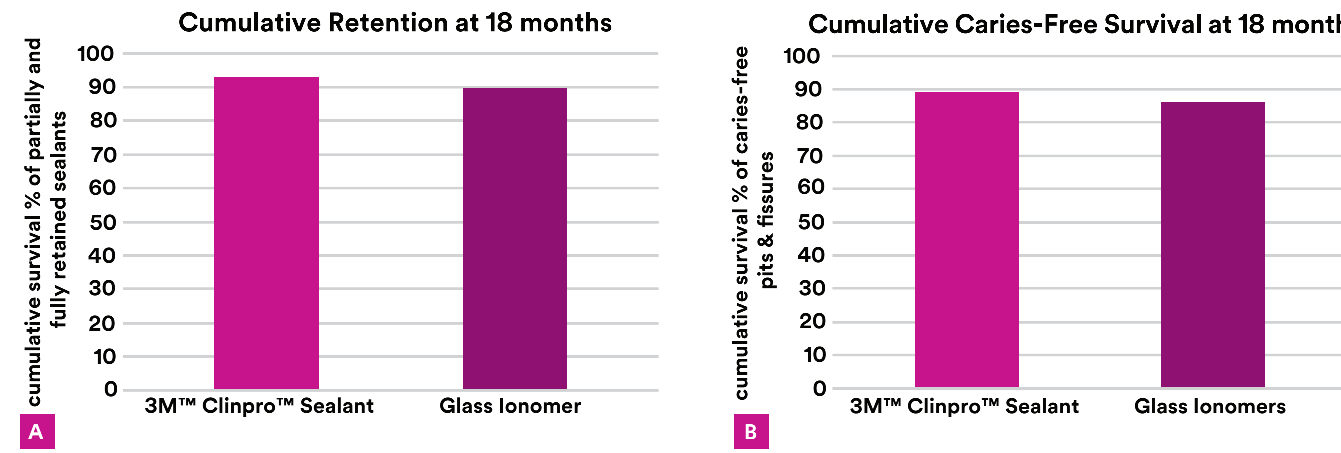


Figure 27: (a) cumulative survival % of partially and fully retained sealants; (b) cumulative survival % of caries-free pits & fissures.
Source: Al-Jobair et al., 2017

In a split-mouth design by Kumaran (2013),[27] 40 children in Kochi, India, received four different pit and fissure sealants, which were evaluated at 6 and 12 months for total retention, partial retention, and total loss. Clinpro Sealant displayed retention that was statistically not different between 6 and 12 months, while Delton® FS+, Helioseal® F, and Fuji VII were statistically lower. Clinpro Sealant showed statistically significantly higher retention rate than Helioseal F and Fuji VII at 12 months.

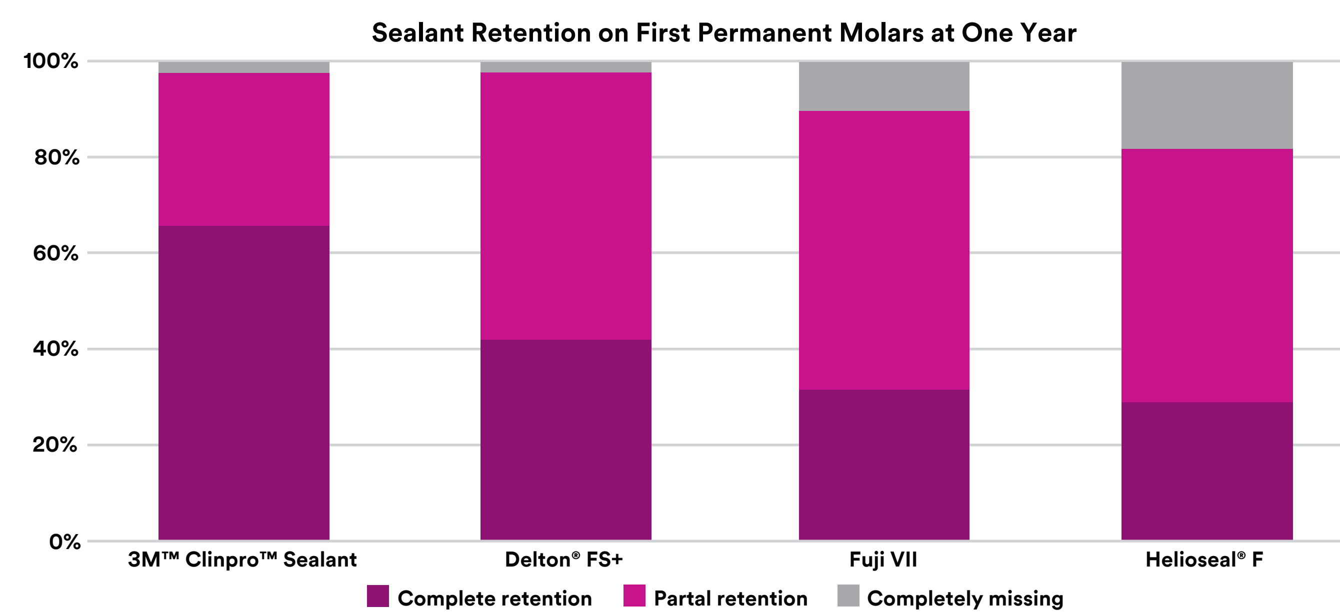


Figure 28: Sealant retention at one year. *Source: Kumaran 2013*

In a study of 80 school children age 7-10 years in Nalgonda, India, by Hasanuddin et al. (2014),[28] sealants were placed with a conventional sealant technique on one side, and an enameloplasty technique on the other side—and evaluated periodically through one year. 3M™ Clinpro™ Sealant had a statistically significantly higher retention rate than Fuji VII after one year.

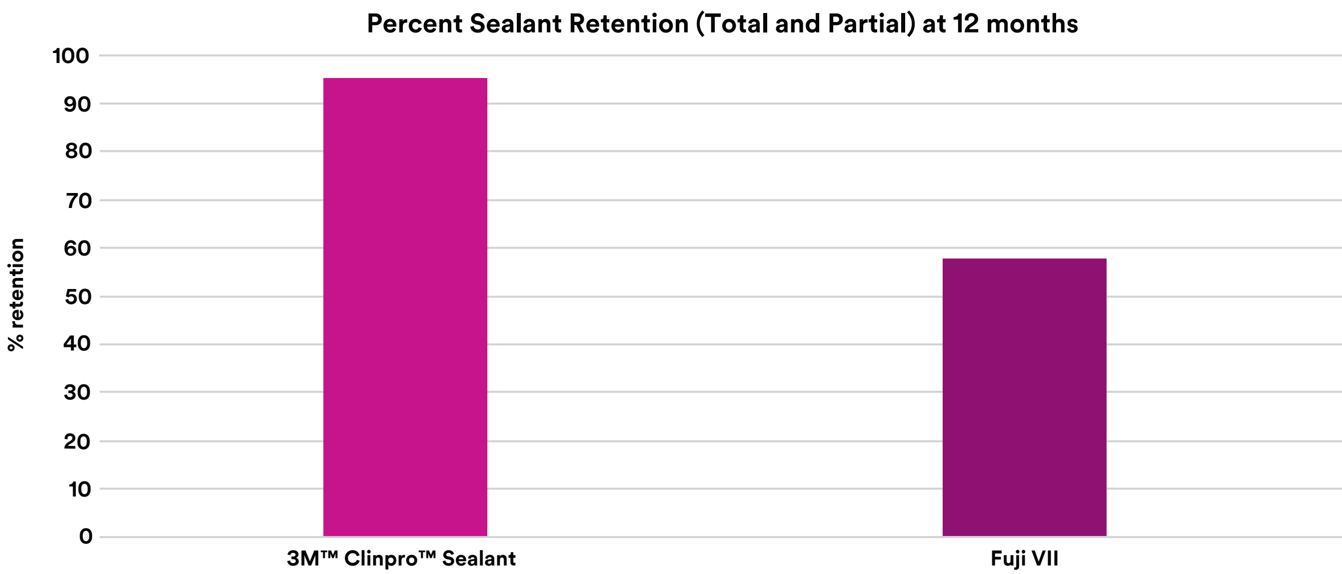


Figure 29: Percent Sealant Retention (total + partial) after one year. *Source: Hasanuddin et al., 2014*

In a split-mouth design by Liu et al. (2014),[29] Clinpro Sealant and a glass ionomer (GI ART) sealant were placed on 383 molars in 280 children in Shenzen, China, with a mean age of 7.8 years. Sealant retention and dentin caries development were monitored through 24 months. The retention of Clinpro Sealant was statistically significantly higher than that of a glass ionomer sealant through 24 months. After two years, 96% of teeth sealed with Clinpro Sealant were caries-free.

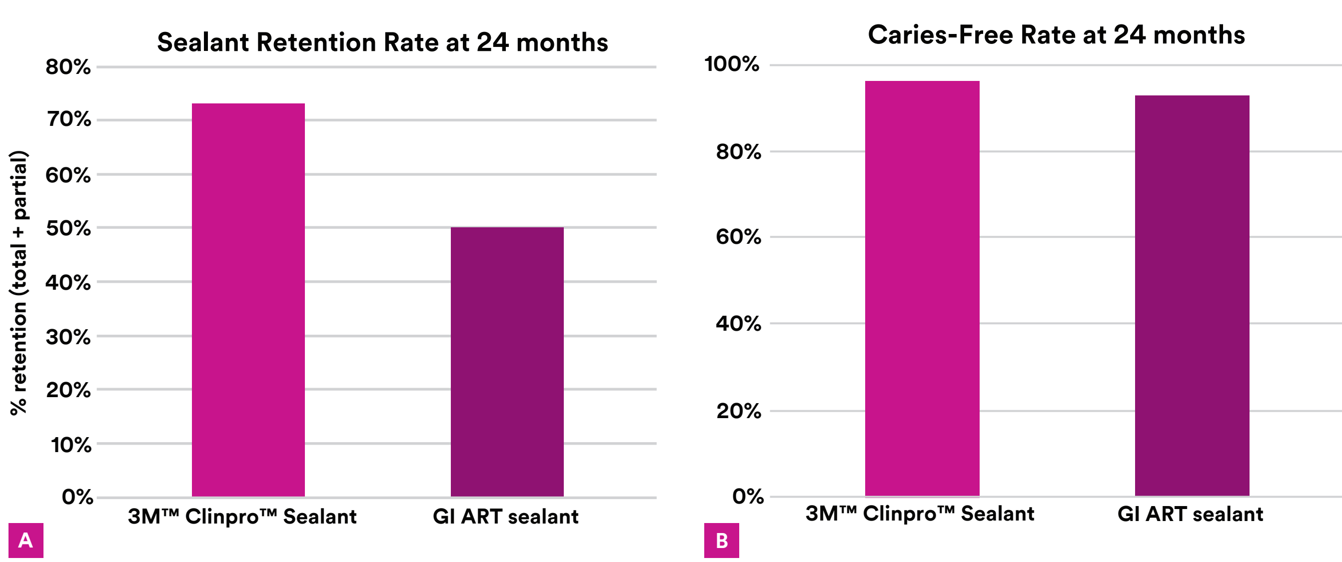


Figure 30: (A) sealant retention rate at 24 months; (B) caries-free rate at 24 months. *Source: Liu et al., 2014*

In a study by Bhat et al. (2013),[30] sealants were placed on newly erupted permanent first molars of 80 children aged 6-9 years in Bangalore, India, who were at high caries risk. Sealant retention and development of caries were evaluated at 6 and 12 months using modified Simonsen's criteria. Retention and caries prevention of 3M™ Clinpro™ Sealant were statistically not different from Embrace™ WetBond™ and Delton® FS+ with Prime & Bond® NT, and statistically better than Fuji VII. Approximately 97% of teeth sealed with Clinpro Sealant were caries-free after one year.

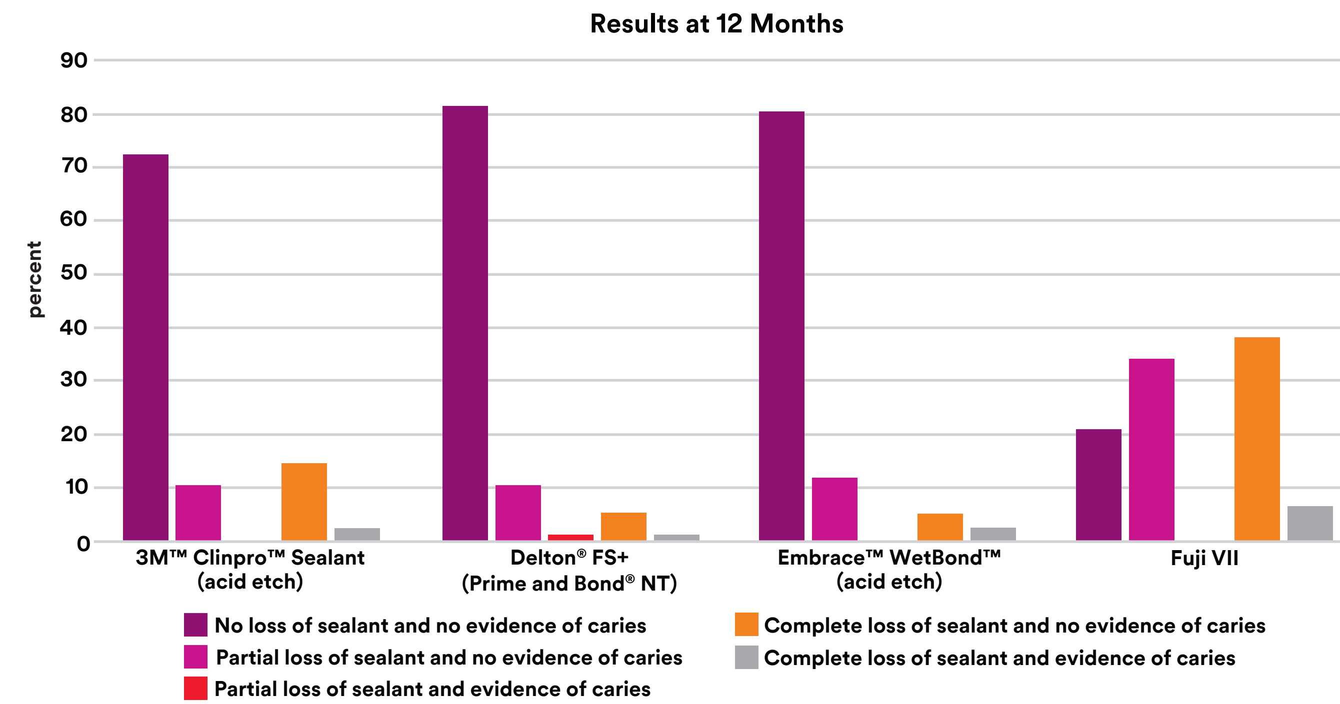


Figure 31: Ratings at 12 months according to modified Simonsen's criteria. *Source: Bhat et al., 2013*

In a randomized split-mouth design study by Reddy et al. (2015),[31] unfilled and filled resin-based sealants were applied on permanent first molars of 56 children ages 6-9 in Tumkur, India. Sealant retention was evaluated bimonthly through 12 months using Simonsen's criteria. After 12 months, the retention rates of unfilled 3M™ Clinpro™ Sealant and filled Helioseal® F sealants were statistically not different. Clinpro Sealant had 96% full or partial retention through 12 months.

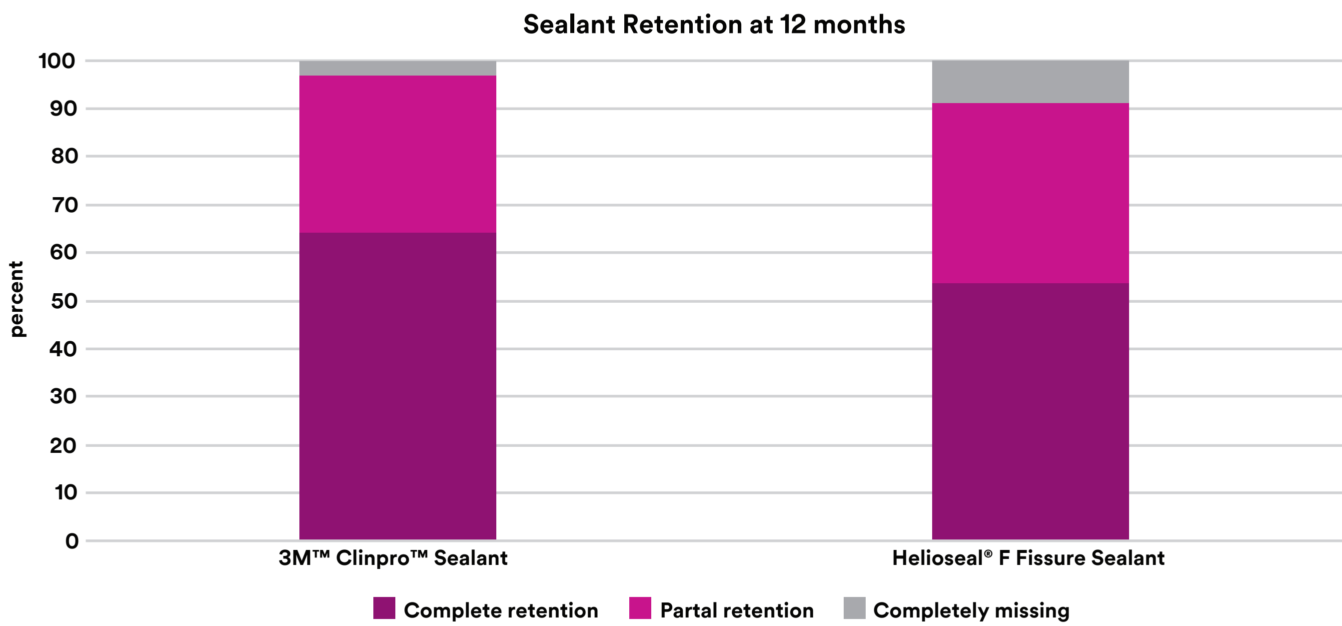
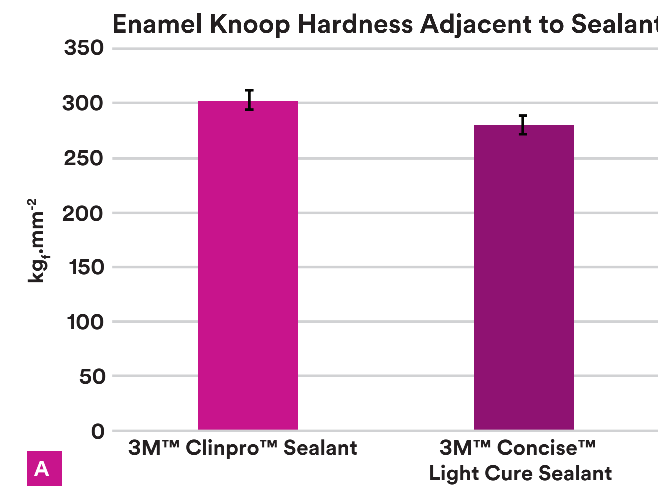


Figure 32: Sealant retention at 12 months. *Source: Reddy et al, 2015*

In a study by Tripodi et al. (2011),[32] Clinpro Sealant, Saremco Microseal, Delton® FS +, and a flowable composite were randomly applied on 2 out of 4 caries-free permanent first molars of 10 patients ages 7-9. Impressions were taken before the sealing material was applied, immediately after application, and 6 months and 1 year after. Wear was analyzed via SEM and image analysis. The wear of Clinpro Sealant was statistically not different from a low-filled sealant, a highly filled sealant, or a flowable composite through one year.

Other Clinical Studies

In a study by Francci et al. (2003),[33] eight volunteers in São Paulo, Brazil, wore palatal appliances containing four human occlusal enamel surfaces for 7 days, and used fluoride-free dentifrice. Knoop microhardness was measured on enamel adjacent to the sealant, and fluoride concentration was measured in the dental plaque that had collected on the sealant. The fluoride levels in plaque were statistically significantly higher for 3M™ Clinpro™ Sealant than a non-fluoride releasing sealant. Knoop microhardness was statistically significantly higher for Clinpro Sealant than a non-fluoride releasing sealant (3M™ Concise™ White Light Cure Sealant), showing that Clinpro Sealant provided better protection to the adjacent enamel.



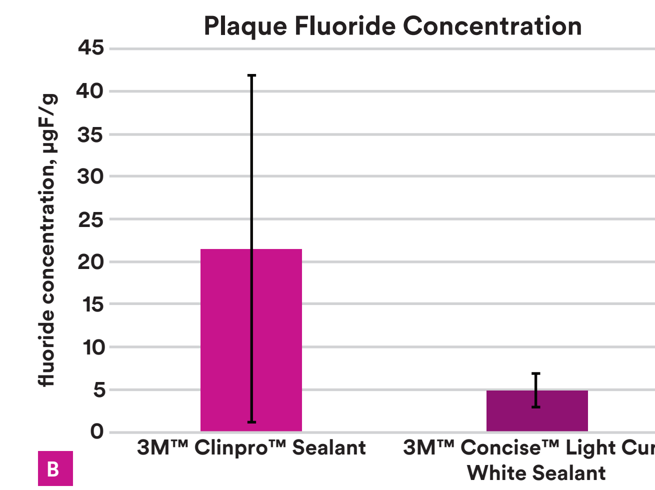


Figure 33: (a) Knoop microhardness of enamel adjacent to the sealant; (b) plaque fluoride concentration. *Source: Francci et al., 2003*

In a study by Gomez et al. (2008),[34] Clinpro Sealant was applied to the interproximal areas of 13 premolars with orthodontic indication for extraction, on both non-cavitated lesion and sound enamel, in seven patients in Valparaiso, Chile. The length of resin tags was measured via scanning electron microscopy on cross sections. The resin tag length on etched enamel was 4.2 microns in non-cavitated lesions and 5.5 microns in sound enamel; they were statistically not different. Resin tags are considered to be indicative of the adaptation and retention of the sealant, and of the ability to flow into the details of the etched enamel surface.

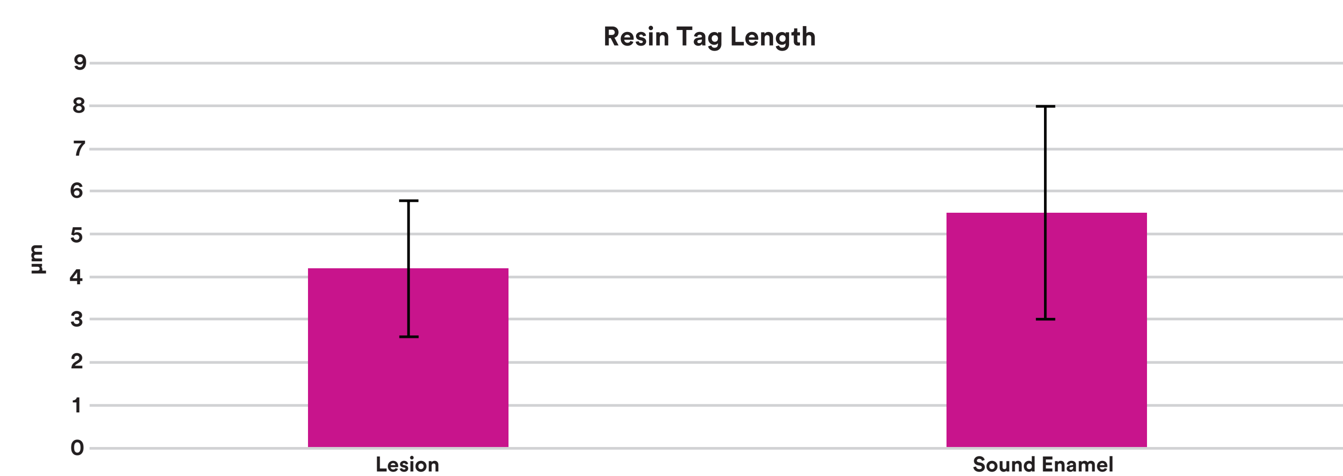


Figure 34: Length of resin tags in non-cavitated lesioned enamel and etched sound enamel. *Source: Gomez et al., 2008*

Frequently Asked Questions

Can I use a bonding agent with 3M™ Clinpro™ Sealant?

Several studies have been conducted with sealants and bonding agents. This technique has been shown to be useful when applying sealant to teeth that are difficult to keep isolated and there is concern about moisture contamination.[35,36]

How will I know how many seconds are needed to cure Clinpro Sealant?

Consult your curing light manufacturer's instructions. 3M lab testing showed Clinpro Sealant required the following cure times to pass the desired Barcol hardness test rating of 30, or higher, on both the top and bottom of prepared samples: All halogen lights (with output of 550-1000 mW/cm^2) 20 seconds. All LED lights (with output 1000-2000 mW/cm^2) 10 seconds.

How many teeth can be sealed with one syringe of Clinpro Sealant?

Each syringe contains approximately 70 applications. However, there are variations among patients that can impact the exact number.

Can I use a fluoride prophy paste to clean the teeth before placing a sealant?

Yes. There were no deleterious effects identified when polishing with either fluoridated or nonfluoridated polishing pastes.[37]

After curing, why is there an air-inhibited layer on the sealant?

The air-inhibited layer is unavoidable with methacrylate curing chemistry used in sealants and composites. Thinner layers will produce a higher level of air inhibition.

Because you are etching the enamel beyond where the sealant will be placed, will this exposed etched enamel now be more susceptible to caries?

The caries process on the occlusal surface is initiated within the fissures not on the cuspal inclines. In addition, it has been shown that etched enamel remineralizes completely within 48 hours due to the deposition of salivary calcium and phosphate salts.[38]

Are sealants covered by insurance?

Most dental insurance companies have coverage for child and adolescent sealants. However, they do not always reimburse the dental professional if a sealant needs to be replaced.

Is a fissurotomy or enamelplasty recommended prior to sealant placement?

Fissurotomy and enamelplasty are no longer recommended for occlusal surfaces that have non-cavitated lesions. These practices result in a loss of healthy tooth structure and have not been shown to increase healthy outcomes.[39,40]

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