Vanish™ XT

Extended Contact Varnish

Technical Product Profile

3M ESPE

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INTRODUCTION

Dentinal Hypersensitivity

Dentinal Hypersensitivity is characterized by a short, sharp pain that is caused by the response of exposed dentin to a thermal, tactile, or chemical stimulus. It has been reported that the prevalence of dentinal hypersensitivity varies from 4 to 57 percent and between 60 and 98 percent in patients with periodontitis.[1] In the forthcoming years prevalence of dentin hypersensitivity is expected to increase as people live longer and retain more teeth.[2]

For dentinal hypersensitivity to occur root dentin must be exposed and dentinal tubules must be open. The most common cited reason for exposed dentinal tubules is gingival recession. Chronic exposure to bacterial plaque, toothbrush abrasion, gingival laceration from oral habits such as toothpick use, excessive flossing, crown preparation, inadequate attached gingiva, and gingival loss secondary to disease or surgery are some but not all causes of gingival recession.[3] Periodontal disease and improper brushing habits can also result in gingival recession accompanied by sensitive teeth.

The most widely accepted theory of tooth sensitivity to date is known as the hydrodynamic theory. This theory was first reported by Gysi in 1900.[4] The theory was extensively studied and corroborated in the 1950s and 1960s by Bränström.[5] Naturally-occurring channels called tubules found in human dentine are in direct contact with the nerve endings. In healthy teeth, these tubules, and therefore the nerve endings, are physically isolated from the oral environment. Tubules in the coronal portion of the dentin are not exposed to the oral environment because the enamel crown covers them. Tubules in the root portion of the dentin also do not naturally come into contact with the oral environment because cementum and healthy gingiva cover them. In the case of recessed gingiva, tubules are not immediately in direct contact with the oral environment because the cementum, which is comprised of organic and mineral debris, covers the tooth root surface. Cementum also fills the outermost volume of the dentin tubules. If the cementum is removed (e.g., by abrasion from tooth brushing, diet-borne acid erosion, etc.) the tubules may be opened. Because these tubules are filled with fluid and are in direct contact with nerve endings, exogenous stimuli are quickly transmitted and nerve polarization occurs which can lead to the sensation of pain.

The two most common methods for treating dentinal hypersensitivity are over-the-counter (OTC) desensitizing toothpastes for home use and topical desensitizing agents for professional use. OTC toothpastes containing a desensitizing active ingredient such as potassium nitrate work by providing a decrease in the excitability of nerves by altering their membrane potential.[1] These home use products require patient compliance to be effective. Professionally applied desensitizing agents are designed to reduce flow through dentin tubules by occluding the tubules. These professionally applied treatment products include resin sealers both with and without fluoride, fluoride-free products that contain glutaraldehyde, fluoride varnishes and fluoride-containing glass ionomers. Glass ionomers are known for their ability to reduce or eliminate sensitivity in restorations[6] and have also been used to treat hypersensitivity.[7]

Caries Protection

Teeth are covered by dental plaque that contains bacteria such as the mutans streptococci (which includes *S. mutans and S. sobrinus*) and *lactobacilli*. These bacteria produce organic acids as they metabolize fermentable carbohydrates. The acids diffuse through dental plaque, to the underlying tooth surface (enamel or dentin, if exposed) and dissociate to produce hydrogen ions. The hydrogen ions dissolve tooth mineral releasing calcium and phosphate into solution. As calcium and phosphate diffuse out of the tooth, demineralization occurs. Left unaltered, demineralization leads to a white spot lesion that eventually leads to a cavity. Saliva naturally combats tooth decay in several ways including buffering (neutralizing) plaque acids and carrying minerals that replace those mineral dissolved from the tooth during demineralization. The natural repair process of replacing mineral is called remineralization. These conditions of demineralization and remineralization occur naturally and constantly in the mouth.

The use of sealants and other tooth coating materials is an effective method of preventing tooth decay. The use of sealants to prevent caries of the occlusal surfaces of teeth is highly recommended.[8] Tooth coating materials placed on other highly susceptible surfaces, such as around orthodontic devices may also be effective in preventing demineralization.[9]

Accompanying reports of declining caries indices and increased fluoride use are reports of an increase in caries among 2 to 11 year olds.[10] It is important to note that occlusal, or pit and fissure caries may account for more than 80 percent of the total caries in children with the first permanent molar being the most frequent site of occlusal caries.[11] This propensity is often explained by the morphological complexity of occlusal surfaces. Deep pits and fissures promote plaque accumulation to a level that is relatively difficult to remove with toothbrushing and therefore inhibits the surfaces from receiving the same level of caries protection from topically applied fluoride as smooth surface enamel.[12] The accumulation of plaque and subsequent caries susceptibility are greatest when molars first erupt.[13] There is therefore a need to provide additional protection for these highly susceptible sites.

Resin based sealants have been used in recent decades to prevent caries in pits and fissures. Glass ionomers have also been used as pit and fissure sealants. Advantages of glass ionomers include their moisture tolerance and release of fluoride to surrounding enamel. These attributes combined have lead to more widespread use of glass ionomer materials as pit and fissure sealants. Some studies suggest that glass ionomer sealants may continue to provide caries protection after the material has been lost.[14,15] Additionally, glass ionomers may serve as an acceptable alternative to resin based sealants on newly erupting teeth where isolation and moisture are a problem.[16]

Fluoride is the only ingredient proven to prevent dental caries.[17] Fluoride inhibits demineralization and enhances remineralization when present in oral fluids. When present during periods of demineralization, fluoride reaches the tooth surface, adsorbs onto mineral surfaces and protects the tooth against dissolution. Fluoride enhances remineralization by adsorbing to the surface and attracting calcium and phosphate ions that are at supersaturation levels in saliva. Fluoridated tooth structure (fluorapatite) has a lower solubility than naturally occurring hydroxyapatite and therefore better resists the inevitable acid challenge.[18] The use of topically applied fluoride has lead to the decline in the prevalence and severity tooth decay and is both safe and effective in preventing and controlling dental caries.[17]

Vanish™ XT Extended Contact Varnish

Vanish™ XT Extended Contact Varnish has been developed specifically for some of these patient situations. This site-specific, durable coating provides a rapid and long-lasting relief from hypersensitivity and can be used as a protective coating on caries risk tooth surfaces. This resin-modified glass ionomer technology in Vanish XT varnish is moisture-tolerant making it suitable for application on wet surfaces such as newly erupted teeth. Additionally it's virtually invisible making it ideal for protecting tooth surfaces around orthodontic brackets and non-cavitated caries lesions. Vanish XT varnish is a durable coating designed to treat exposed root surface sensitivity and to be used as a site specific protective coating for newly erupted teeth and other high risk, caries prone areas (e.g. around orthodontic and acid erosion) including non-cavitated lesions.

PRODUCT DESCRIPTION

Vanish XT varnish is a site-specific, protective coating for enamel and dentin tooth surfaces. It is a highly durable coating that can remain on the tooth for six months or longer. The XT in the product name is intended to reflect the product's properties as an "extended varnish", having a long-term durability with fluoride release.

It is a light-cured glass ionomer material in a two-part liquid/paste system. The liquid/paste materials are contained in the Clicker™ Dispensing System manufactured by 3M ESPE. This dispensing system provides simultaneous dispensing of each component for a consistent ratio. The paste contains a radiopaque fluoro-aluminosilicate glass. The liquid contains a modified polyalkenoic acid. Vanish XT varnish provides the major benefits of glass ionomer materials including adhesion to tooth structure and sustained fluoride. In addition, Vanish XT varnish provides the added benefit of calcium, and phosphate release. Vanish XT varnish offers a combination of a prolonged working time with a short set time achieved by light curing.

INDICATIONS

Vanish XT varnish is indicated for:

- Treatment of exposed root surface sensitivity
- Site specific protective coating for newly erupted teeth and other tooth surfaces (e.g. around orthodontic and acid erosion) including non-cavitated lesions

Vanish XT varnish is:

- Not intended as a replacement for long-term conventional sealants
- Not to be used under orthodontic brackets
- Not to be used in patients with dry mouth (e.g. patients who may awaken with a dry mouth due to open-mouth breathing)

COMPOSITION

Vanish XT varnish is a resin modified glass ionomer (RMGI) based on the patented methacrylate modified polyalkenoic acid. This technology was first commercialized in 3M™ ESPE™ Vitrebond™ Glass Ionomer Liner/Base, as well as other 3M ESPE dental materials. The liquid component consists primarily of polyalkenoic acid, HEMA (2-hydroxethylmethacrylate), water and initiators (including camphorquinone) plus calcium glycerophosphate. The paste is a combination of HEMA, BIS-GMA, water, initiators and fluoroaluminosilicate glass (FAS glass).

The patented resin modified glass ionomer chemistry in Vanish™ XT Extended Contact Varnish provides a burst of fluoride released during the first several days after placement and also long term sustained fluoride release over the life of the coating. The fluoride resides in fluoroaluminosilicate glass particles: reaction at the surface provides the immediate release, while the bulk provides a reservoir of fluoride for sustained release.

Vanish XT varnish also contains calcium glycerophosphate, which can provide calcium and phosphate release, and whose benefit in oral care has been demonstrated.[19, 20] The calcium glycerophosphate in Vanish XT varnish provides continual release of calcium and phosphate over the life of the coating.

PHYSICAL PROPERTIES

The following is a presentation of the key properties of Vanish XT varnish. Testing was conducted by 3M ESPE unless otherwise noted.

Wear Rate/Toothbrush Abrasion

Resistance to wear from toothbrushing, is an important property of a protective coating. Vanish XT varnish provides a protective coating that lasts between typical dentist appointments of six months. *In vitro* laboratory testing indicates the coating will remain on the tooth and resist abrasion from toothbrushing for at least 6 months. Scanning Electron Microscopy (SEM) Figures 1 and 2 below, show how the surface of the remaining coating appears after 2000 and 5000 brush strokes, respectively. Additionally, Vanish XT varnish resists toothpaste abrasion at least as good as GC Fuji Triage™, as shown in Figure 3.

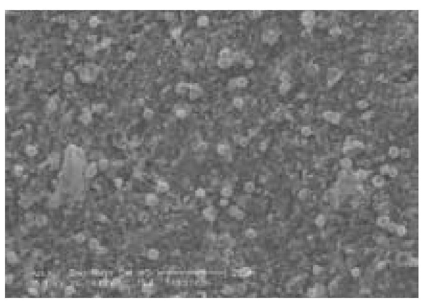


Figure 1. 1000X magnification: Surface of Vanish™ XT Extended Contact Varnish on dentin after 2000 strokes, showing that the coating is intact.

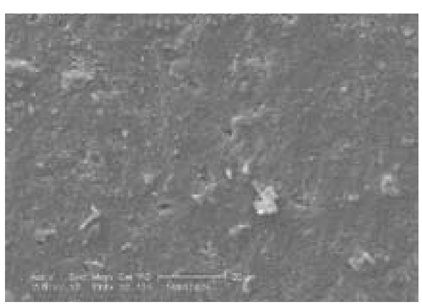


Figure 2. 1000x magnification: Surface of Vanish™ XT Extended Contact Varnish on enamel after 5000 strokes, showing that the coating is intact.

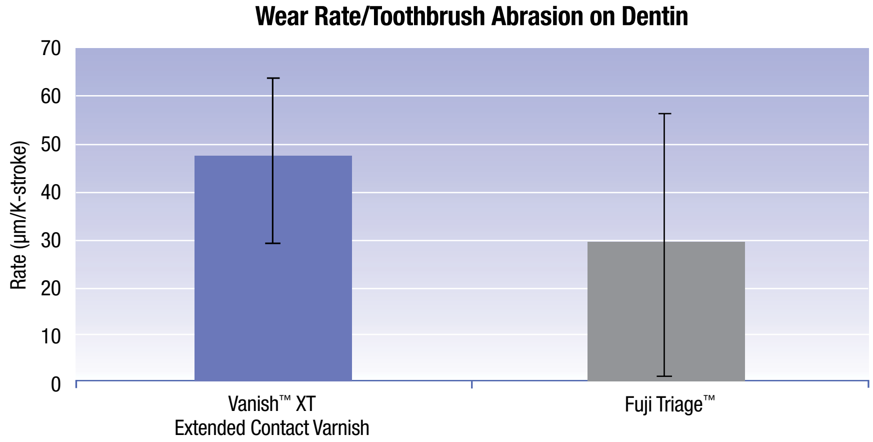


Figure 3. Wear Rate/Toothbrush Abrasion on Dentin

Toothbrush Abrasion, Dentin sample preparation

Bovine tooth samples were embedded in acrylic and ground with silicon carbide abrasive (Grade 120) to remove then enamel and expose the underlying dentin. Samples were then polished with a silicon carbide abrasive (Grade 320). The polished dentin surface was etched for 30 seconds with 3M™ ESPE™ Scotchbond™ Etchant, to remove material from dentin tubules, and then rinsed thoroughly. These samples represent open tubules that cause root sensitivity. Vanish XT varnish was applied in a thin layer to the moist surface and light cured for 20 seconds; the samples were kept hydrated at all times after curing.

Toothbrush Abrasion Test Method

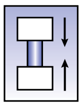
The coated dentin specimens were brushed in an oscillating toothbrushing machine with an ORAL-B™ 35 Soft Straight toothbrush under a load of 450 grams at a frequency of 150 cycles/min (2.5 hz). The sample surface and toothbrush were immersed in a slurry of 50/50 by weight Crest™ Cavity Protection Fluoride Anticavity Toothpaste toothpaste/distilled water during the brushing process. Toothbrushing on each dentin sample was stopped after 2000 strokes. This procedure was repeated using polished bovine enamel specimens also coated with a thin layer of material. Enamel specimens received 5000 brushing strokes. The conditions of this *in vitr*o toothbrushing experiment have been previously correlated to *in vivo* toothbrushing conditions.

Compressive and Diametral Tensile Strength

Compressive and diametral tensile are two common strength measurements for dental materials. Both measurements are designed to represent forces the materials will be exposed to during chewing. With compressive strength, rods are made of the material and simultaneous forces are applied to the opposite ends of the sample length. Failure is the result of shear and tensile forces. Diametral tensile strength is a measurement obtained when compressive forces are applied to the sides of a sample until fracture occurs.

A higher compressive and diametral tensile strength value is desirable. As shown in Figures 4 and 5, the compressive and diametral strength of Vanish™ XT Extended Contact Varnish is not statistically different from GC Fuji Triage™.

Figure 4: Compressive Strength



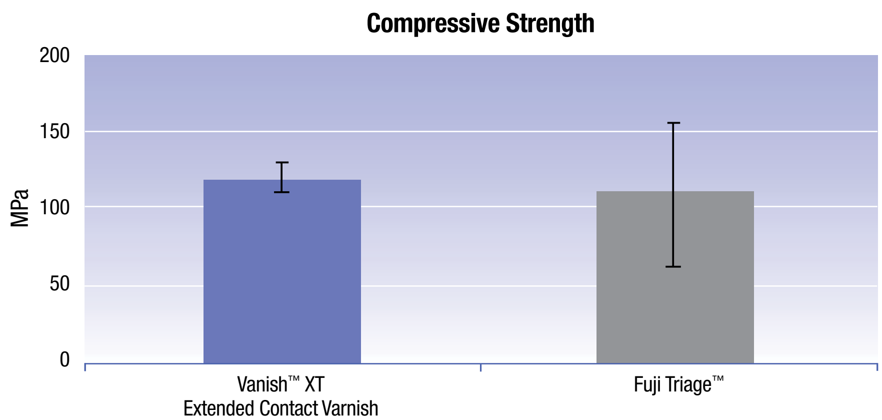
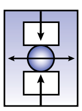
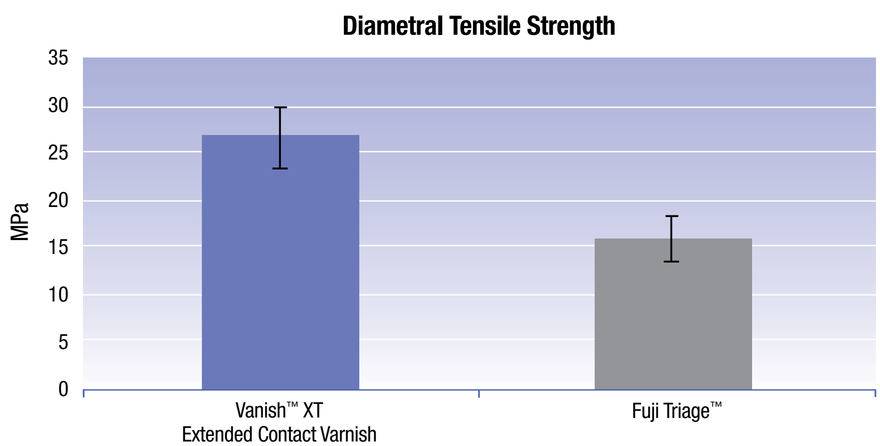


Figure 5: Diametral Tensile Strength





Bond Strength

Vanish XT varnish was also tested for adhesion to bovine teeth using a shear wire-loop method. Table 1 shows the results of testing on open tubule dentin, smear-layer covered dentin, and uncut enamel.

Table 1. Vanish™ XT Extended Contact Varnish Shear Bond Strengths

Shear Bond Strengths Vanish™ XT Extended Contact Varnish Mpa (StDev)		
Open Tubule Dentin	**Smear-Layer Covered Dentin**	**Uncut Enamel**
6.44 (2.87)	9.42 (1.69)	17.8 (2.4)

Bond Strength Sample Preparation

Bovine enamel and dentin specimens were prepared and etched for 30 seconds with 3M™ ESPE™ Scotchbond™ Etchant and then rinsed thoroughly. In addition, bovine enamel specimens still containing a smear layer (i.e., unetched) were also included.

A small cylinder (5mm diameter by 0.3mm thick) of material was applied to each specimen, then 3M™ ESPE™ Filtek™ Z250 Universal Restorative was placed on top of the coating material (to serve as an anchor). Following 24 hours of aging in 37°C deionized water, adhesion was evaluated using the wire-loop shear method.

Fluoride and Calcium Release

Vanish XT varnish contains fluoride as a part of a reactive fluoroaluminosilicate glass. Fluoride has been shown to reduce the incidence of caries.[8] The cumulative fluoride release of Vanish XT varnish during the first 24 hours and beyond are shown in Figures 6 and 7 respectively. During the first 24 hours, the cumulative fluoride release of Vanish XT varnish is statistically higher than Colgate® Duraphat®, a conventional sodium fluoride containing varnish. Beyond 24 hours, Vanish XT varnish exhibited a higher cumulative fluoride release than Fuji Triage and Pulpdent® Embrace™ Wetbond™ pit and fissure sealant.

The calcium glycerophosphate in Vanish XT varnish provides continual release of calcium and phosphate over the life of the coating. Calcium glycerophosphate can provide calcium and phosphate release. The benefit of calcium and phosphorous has been demonstrated in oral care.[19,20]

Vanish XT varnish releases phosphate (Figure 8) and exhibits a higher cumulative calcium release than Fuji Triage (Figure 9).

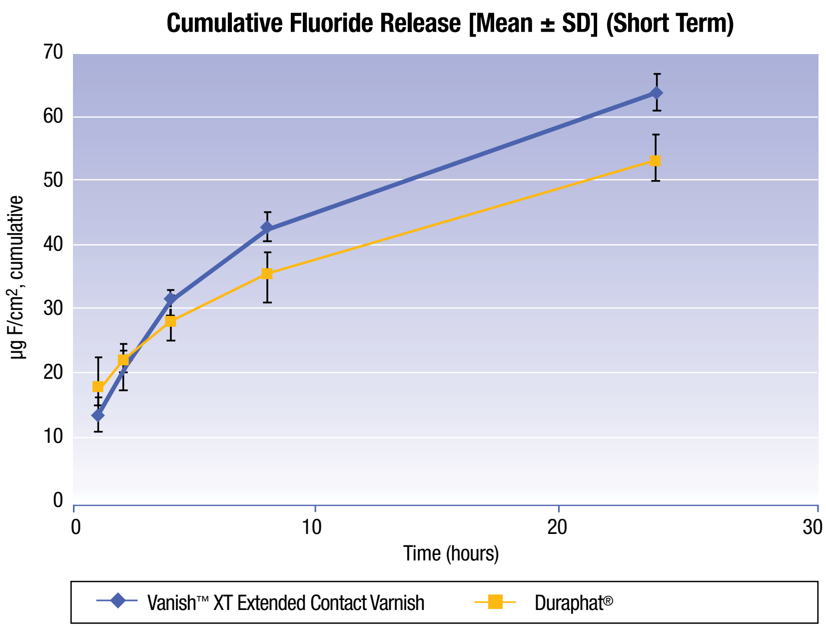


Figure 6. Cumulative Fluoride Release – first 24 hours

Figure 7. Cumulative Fluoride Release – beyond 24 hours

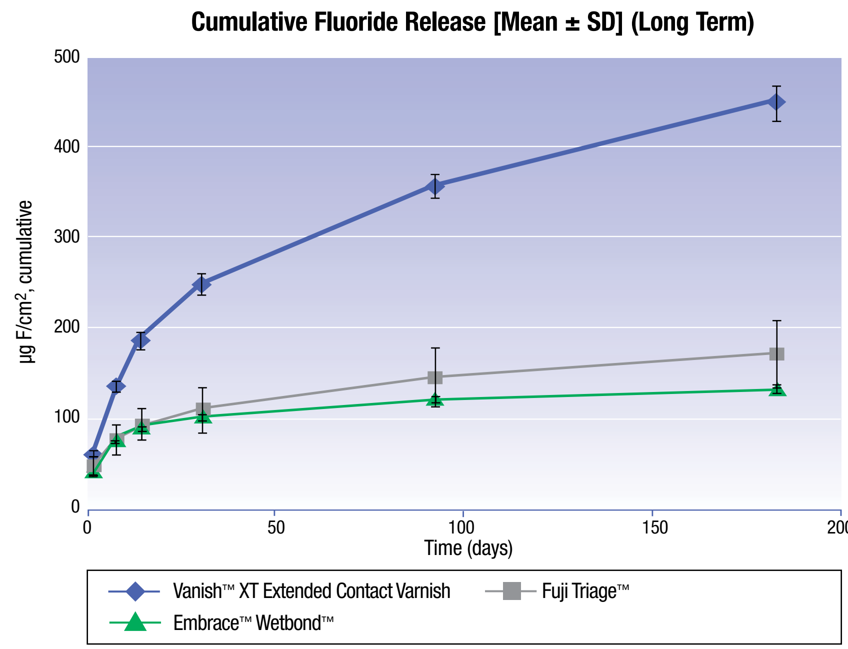


Figure 8. Cumulative Phosphate Release

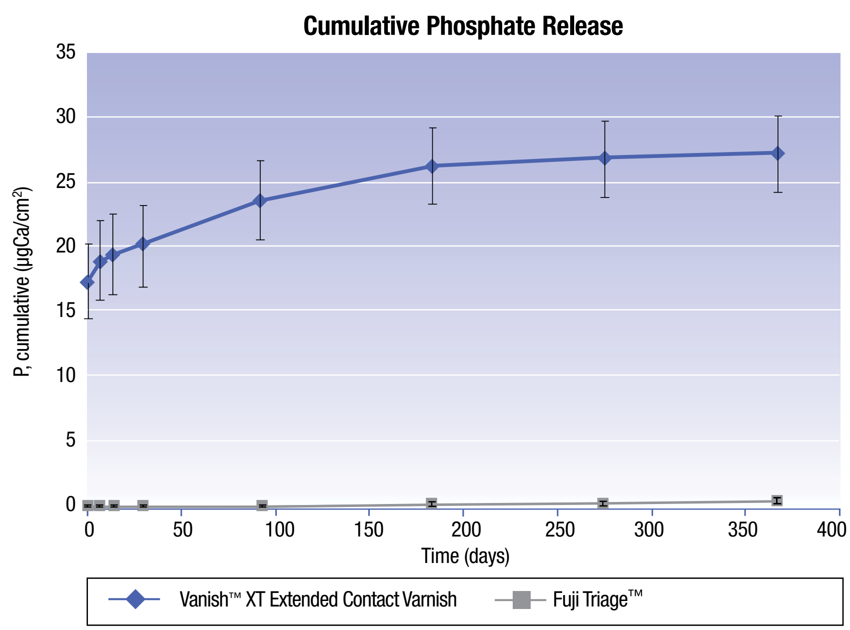
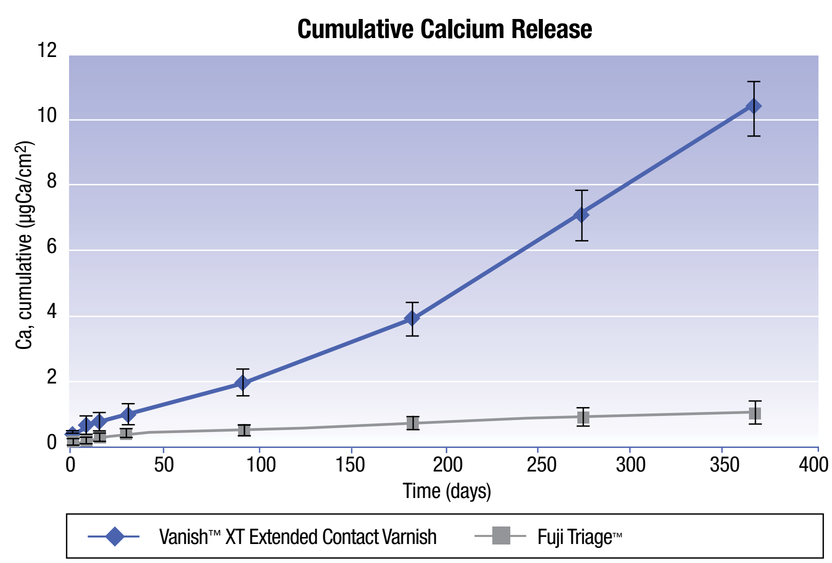


Figure 9. Cumulative Calcium Release



Sample Preparation

Discs (1mm thick by 20mm) of each curable material were prepared following manufacturer's instructions. The fluoride varnish was applied in a 1"x1" area onto the frosted portion of a glass microscope slide. Samples were then separately suspended in 25ml deionized water and stored in a 37°C oven. Fluoride, calcium and phosphate released from the materials were determined over the course of the experiment using a fluoride ion selective electrode and inductively coupled plasma spectrometer (ICP) respectively.

Fluoride Recharge

The ability of glass ionomer materials to take up fluoride from dentifrice or oral rinses and then release it has been labeled "recharge" and is a valuable attribute of these materials. As shown in Figures 10 and 11, Vanish XT varnish demonstrates a fluoride recharge effect that lasts up to 4.5 hours after dentifrice/toothpaste application. This recharge effect is repeatable.

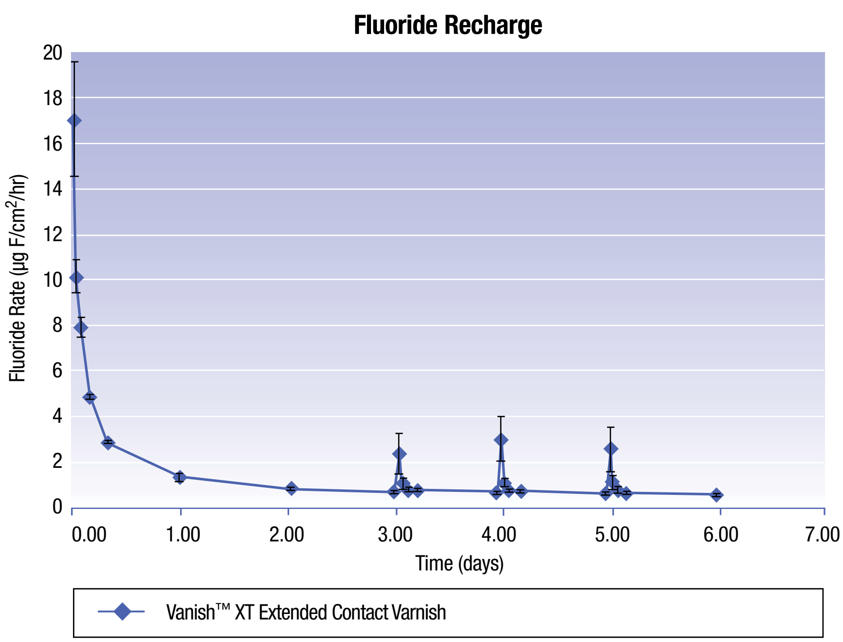


Figure 10. Fluoride recharge effect within first 6 days with ControlRx™ 1.1% Sodium Fluoride 5000 ppm F- Dentifrice, 1 min application

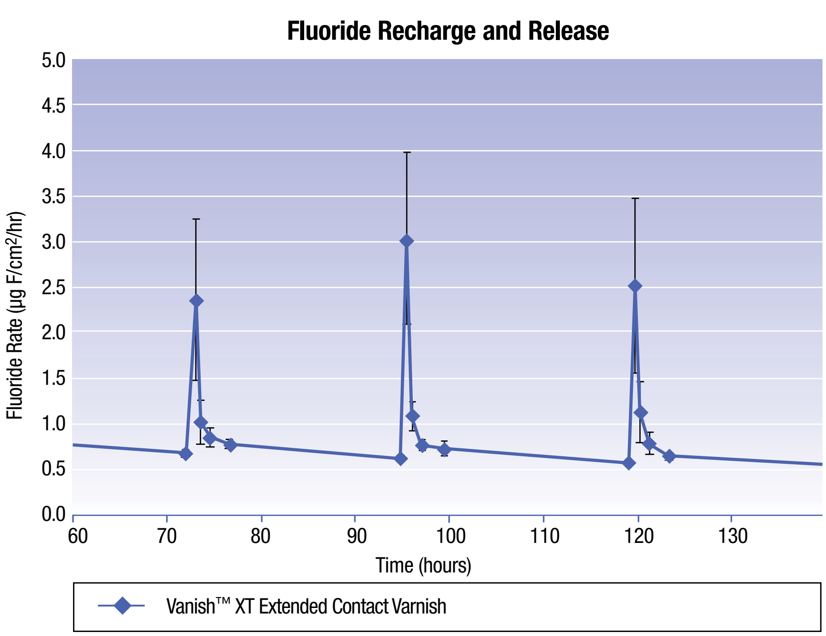


Figure 11. Fluoride recharge effect (hours) with ControlRx™ 1.1% Sodium Fluoride 5000 ppm F- Dentifrice, 1 min application

Fluoride Recharge Method

Fluoride release was measured periodically until it reached a steady state (72 hrs); then, a freshly prepared dentifrice and water slurry was applied once daily for three days, and fluoride release rate measured before and after. The dentifrice used for the recharge treatments was 3M™ ESPE™ ControlRx™ 5000 ppm Fluoride Prescription Dentifrice. ControlRx dentifrice is a prescription-strength anticavity dentifrice with 1.1% sodium fluoride.

Dentin Permeability

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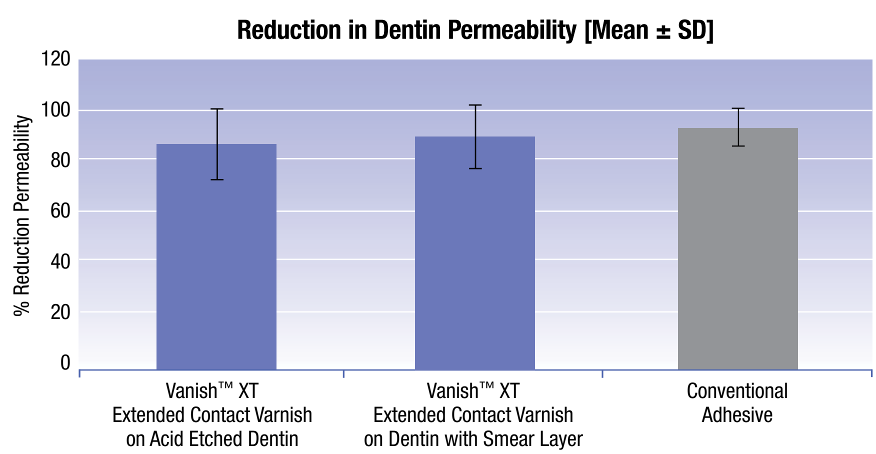
Regents' Profession of Oral Biology & Maxillofacial Pathology
School of Dentistry
Medical College of Georgia

A well-established *in vitro* performance test conducted under the direction of Professor David H. Pashley was used to determine the ability of Vanish™ XT Extended Contact Varnish to reduce dentin permeability using extracted human teeth.

Vanish XT varnish was shown *(in vitro)* to reduce dentin permeability similar to a conventional non-fluoride releasing adhesive (Figure 12).

Figure 12. Permeability Reduction



Sample Preparation

Human tooth crowns cut from unerupted third molars were cemented to plexiglass slabs that were fitted with a stainless steel tube. The tube was used to fill the pulp chamber with water and was attached to a device that measured fluid movement through the dentin. The occlusal surface of each crown was also removed to expose coronal dentin. The coronal dentin was etched with 37% phosphoric acid for 15 seconds. This model is designed to represent exposed tubules typical of root sensitivity. The dentin was coated with either a conventional non-fluoride releasing adhesive or Vanish XT varnish. Reduction in dentin permeability was determined by comparing flow of water through coated specimens to the flow of water through uncoated (prior to application) specimens.

Scanning Electron Microscopy (SEM)

Samples were prepared for examination by SEM as follows. The labial enamel of bovine teeth were cut off in a slow-speed saw to expose the dentin. The dentin was etched for 30 seconds with 3M™ ESPE™ Scotchbond™ Etchant Gel to expose the dentin tubules. Vanish XT varnish was applied in a thin layer to the moist dentin surface and light cured for 20 seconds. The sample was then dried at about 80°C for several hours; this fractured the tooth slab into several sections, suitable for obtaining a cross-section view of the subsurface. Figures 13, 14, and 15 show that Vanish XT varnish physically blocks and penetrates open dentin tubules that can cause sensitivity.

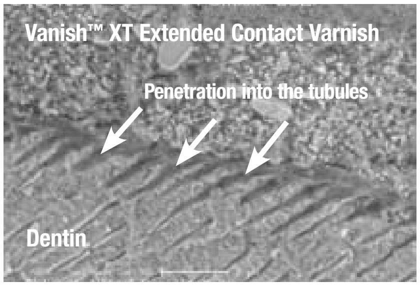


Figure 13. SEM shows Vanish™ XT Extended Contact Varnish blocks and penetrates into dentin tubules.

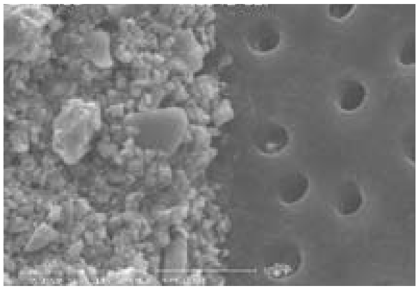


Figure 14. (3000x magnification)

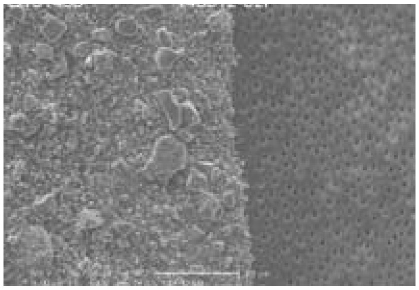


Figure 15. (500x magnification)

Figures 14 and 15 show Vanish XT varnish after application to dentin. Exposed dentin tubules can be seen on the right; Vanish XT varnish physically blocking (or covering) the dentin tubules can be seen on the left.

In vitro Artificial Caries Inhibition

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Minnesota Dental Research Center for Biomaterials and Biometrics
University of Minnesota School of Dentistry

A well-established *in vitro* performance test conducted under the direction of Assistant Professor Daranee Versluis-Tantbirojn was used to evaluate the ability of Vanish™ XT Extended Contact Varnish to protect enamel against a simulated cariogenic challenge.

Vanish XT varnish forms a barrier on teeth to protect against demineralization. Vanish XT varnish inhibited lesion initiation and progression both under the coating and surrounding the coating significantly greater than a conventional resin sealant (Figure 16).

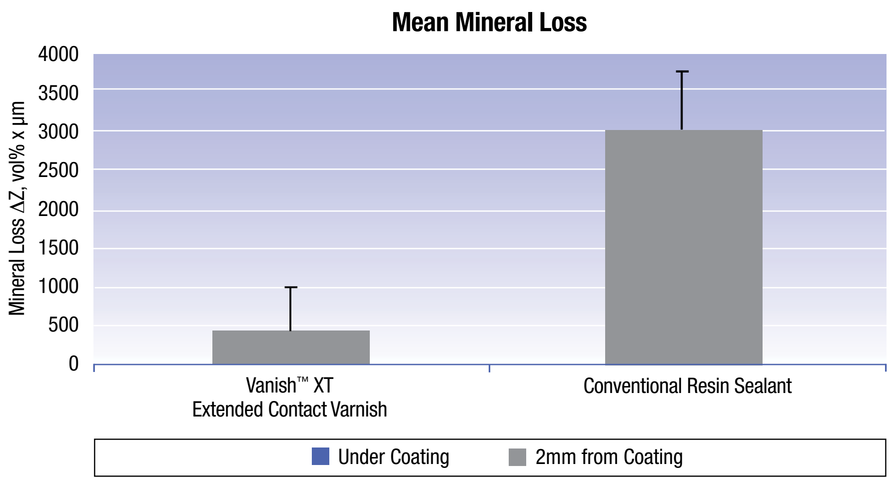


Figure 16. Mineral Loss

Test Method

As illustrated in Figure 17, polished bovine enamel specimens were partially coated with acid resistant nail polish (to serve as an untreated control) and partially coated with test material, then placed in 0.1M lactic acid gel for 20 days at 37°C as a simulated cariogenic challenge. Mineral loss (ΔZ) was determined by cross-sectional microhardness of the enamel both under the coating and adjacent to the coating (i.e., 2mm from the coating).

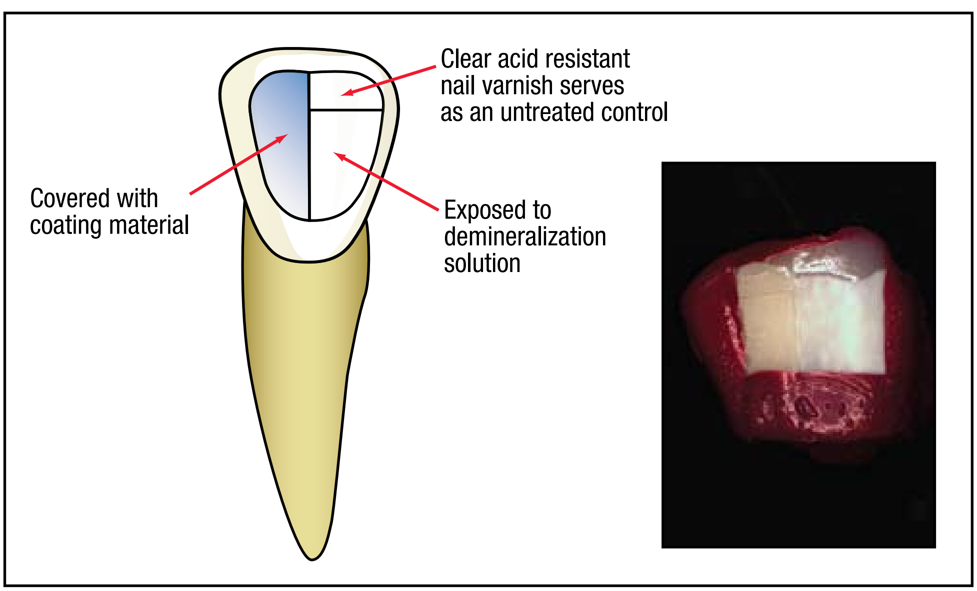


Figure 17. Schematic of coated, uncoated, and regions protected by acid-resistant nail polish

Acid Barrier Test

An *in vitro* study was conducted to determine whether Vanish XT varnish provides an effective physical barrier against acid. Vanish XT varnish, along with a positive control (polyester film) and a negative control (Whatman paper filter #54), were placed between two chambers. One chamber contained acid and the other chamber contained deionized water. The acid chamber contained either phosphoric (pH~0), lactic (pH~1.6), or citric (pH~1.3) acid. Following 20 minutes of exposure, the change in pH of the deionized water was measured to determine whether or not acid was able to traverse the different materials.

The different acids were chosen to represent different acid exposures the coating film might be exposed to. Thirty-seven percent phosphoric acid represented many acidic foods and beverages, such as cola beverages. A 1.0M solution of lactic acid (pH~1.6) represented the acid produced by cariogenic bacteria and a 10% solution of citric acid (pH~1.3) represented citrus fruits and juices.

As shown in Table 2, the pH of the deionized water chamber remained unchanged after 15 minutes exposure to the acids.

Table 2. Average change in pH from the initial value for the time shown (ΔpH @time).

ΔpH	Time (min)	37% H3PO4, pH~0	1.0M Lactic, pH~1.6	10% Citric, pH~1.3
Polyester film	20	0±0 (5)	0±0 (5)	0±0 (5)
Whatman Filter #54	2	5±0 (5)	3.4±0 (5)	3.1±0 (5)
Vanish™ XT Extended Contact Varnish	20	0±0 (5)	0+0 (5)	0+0 (5)

Remineralization

Kevin J. Donly, D.D.S., M.S.
Professor and Chair
Department of Pediatric Dentistry, Dental School
University of Texas Health Science Center at San Antonio

An *in vitro* performance test was conducted under the direction of Dr. Kevin J. Donly to determine the remineralization potential of Vanish XT varnish to that of a conventional, fluoride-containing sealant.

Vanish XT varnish was shown to help remineralize softened enamel more effectively than a conventional resin sealant (Figure 18) and was also shown to help remineralize the softened enamel adjacent to the coating.

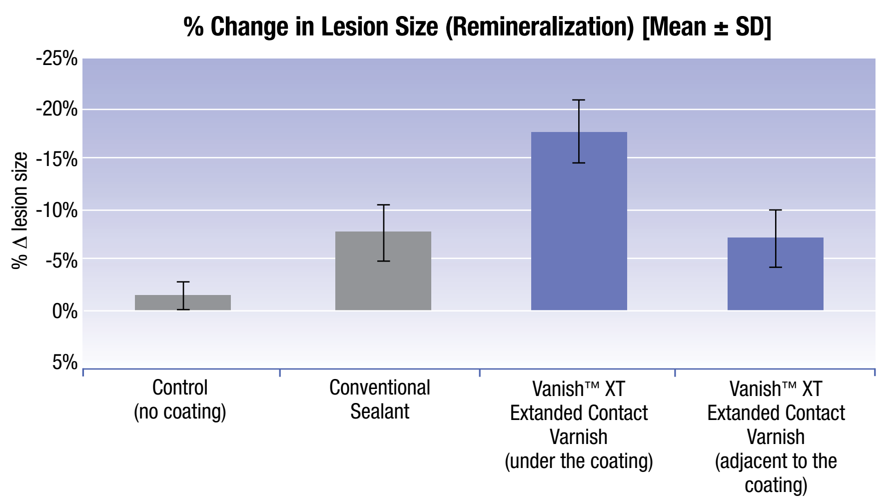


Figure 18. Percent change in lesion size

Sample Preparation

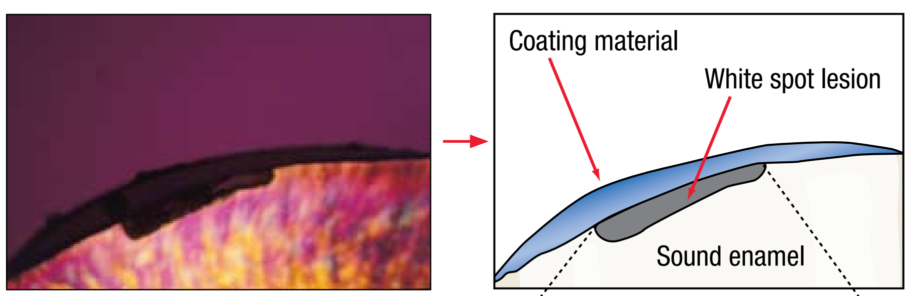
Caries-free, human permanent molars were cleaned then covered with an acid-resistant nail polish, leaving a window of 1 x 5mm uncovered. Teeth were suspended in an artificial caries solution (pH 4.5) to create an artificial caries-like lesion. Teeth were then placed into groups of ten. Groups of specimens were then exposed to one of the following treatments.

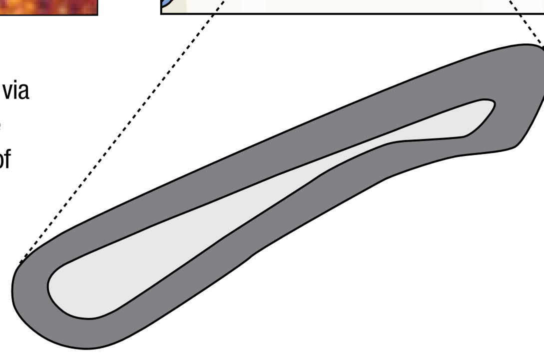
- Control (uncoated) – Served as the positive control and demonstrated the extent to which the artificial saliva promoted remineralization.
- Conventional Sealant (under the coating) – Served as the negative control and demonstrated that the remineralization conditions may be inhibited by an impervious barrier.
- Vanish™ XT Extended Contact Varnish (under the coating) – Experimental group that releases fluoride, calcium and phosphate ions.
- Vanish XT varnish (adjacent to coating) – Experimental group that releases fluoride, calcium and phosphate ions, applied to only ½ of the surface. Allowed measurement of local (rather than under) remineralization potential.

Following treatment, teeth were then sectioned longitudinally to obtain 100μm sections containing artificial caries-like lesion. The sections were photographed with polarized light microscopy in an imbibition media of Thoulet's 1.41 solution, representing a minimum of 10% pore volume. Acid-resistant nail polish was applied to the cut surfaces of the sections, allowing only the natural tooth surface, including the caries-like lesion and treatment incurred for each group, exposed. Sections were then placed in separate, sealed vials with a fluoride-free artificial saliva solution that was replaced every 48 hours. The teeth were brushed once daily with distilled deionized water for one minute and maintained at 37°C (pH 7) with constant circulation for 30 days. After 30 days the specimens were removed and photographed under polarized light, as previously described.

Percent remineralization was determined by comparing lesion pore volumes after 30 days of treatment to baseline lesion pore volumes as illustrated in Figure 19.

Figure 19. Schematic of lesion pore volume





Polarized light microscopy (PLM) measures the absence of mineral via pore volume. The greater the pore volume is, the greater the extent of demineralization.

*Dark grey = 10% mineral loss (less severe demineralization)

*Light grey = 25% mineral loss (more severe demineralization)

Surface Roughness

Average roughness (R_a) is the arithmetic average deviation of peaks and valleys of a surface from the mean line; it is a useful parameter for characterizing surface roughness. A lower R_a value represents a smoother surface. As shown in Figure 20, Vanish XT varnish exhibits a similar coating smoothness to Fuji Triage™, Ultradent® Ultraseal XT™ Plus, and Pulpdent® Embrace™ Wetbond™.

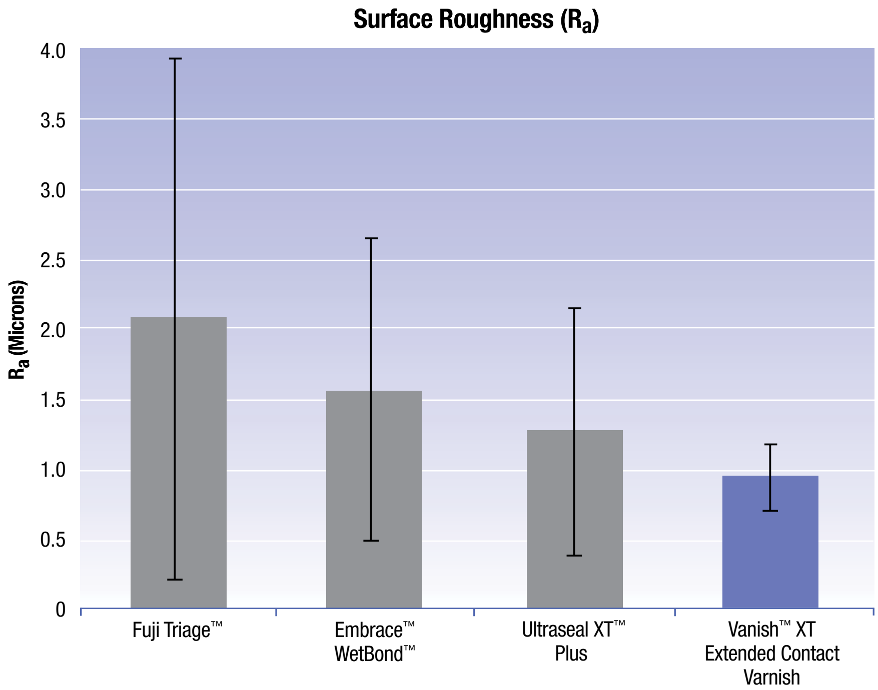


Figure 20. Average surface roughness (R_a) of the coating materials

Surface Roughness Test Method

Each material was placed in a disk-shaped mold and then struck off with a spatula to leave a smooth surface before light curing in a light curing unit. The R_a measurement was calculated from traces on each sample with a contact profiler.

DELIVERY

Vanish XT varnish is packaged in the unique 3M™ ESPE™ Clicker™ Dispensing System; winner of the 2005 Medical Design Excellence Award. The Clicker™ Dispensing System provides simultaneous, pre-measured, and uniform amounts of each component. A consistent ratio of component assures a consistent product. The Clicker dispensing system delivers a consistent A:B ratio regardless of amount in the clicker, age of the material, (within its shelf life) or operator. Vanish XT varnish in the clicker dispenses approximately 80 clicks.

CUSTOMER INPUT

161 dentists in the United States evaluated Vanish™ XT Extended Contact Varnish. During the evaluation period, dentists placed 2000 exposed root sensitivity applications, 500 early erupting molar applications, 800 applications around orthodontic brackets, and 1300 other tooth surfaces including non-cavitated lesions. After utilizing Vanish XT varnish, the evaluators completed a questionnaire to report their experience with the use of this product.

Figure 21. 94% of evaluators rated the viscosity of Vanish™ XT Extended Contact Varnish between 2 and 4.

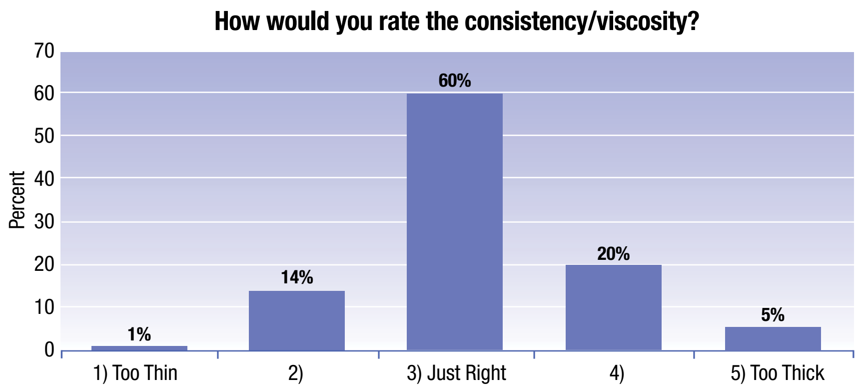


Figure 22. 95% of evaluators confirmed the dispensing of Vanish™ XT Extended Contact Varnish was easy and 99% confirmed that the dispensing was reliable.

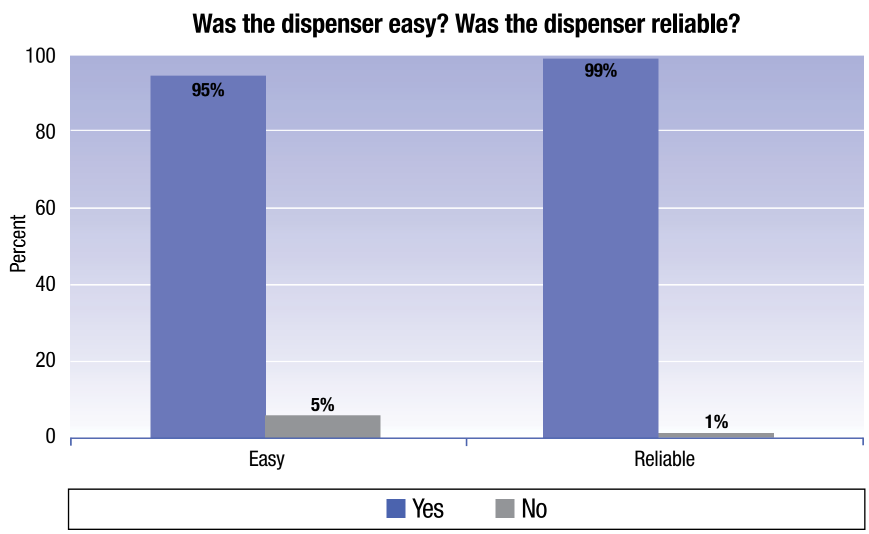
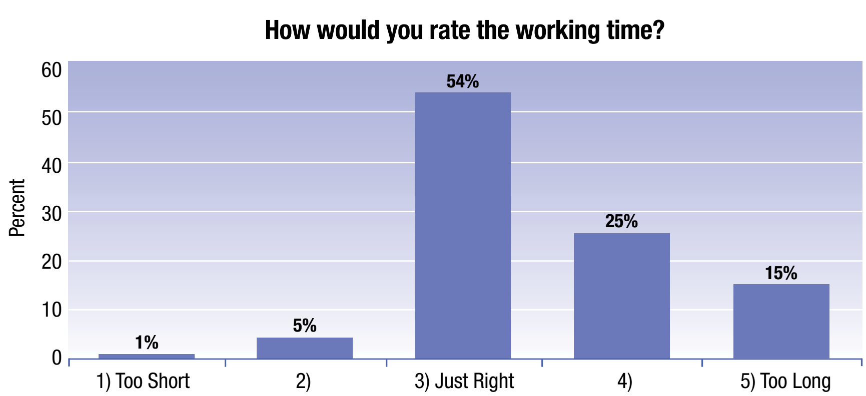


Figure 23. 84% of evaluators rated the working time of Vanish™ XT Extended Contact Varnish between 2 and 4.



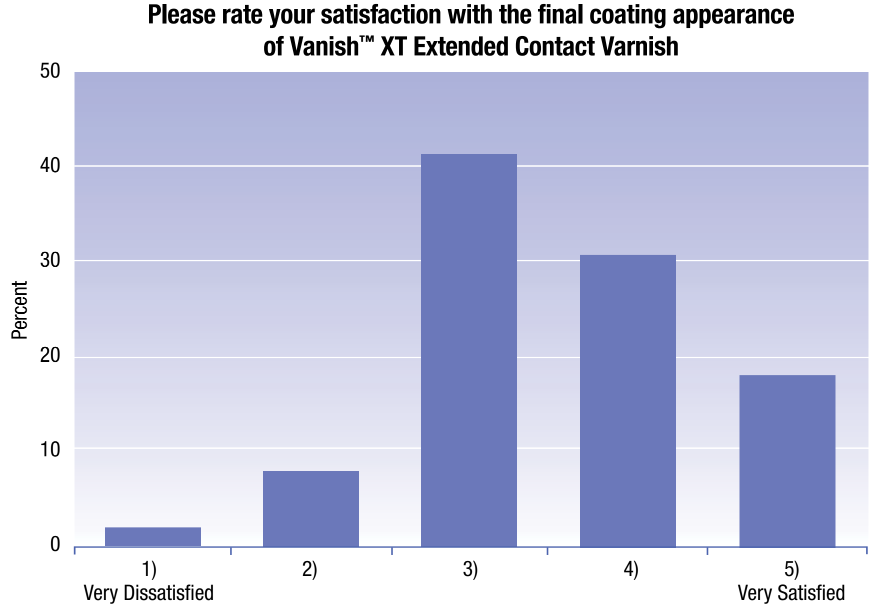


Figure 24. 90% of evaluators rated the final coating appearance of Vanish™ XT Extended Contact Varnish >/=3.

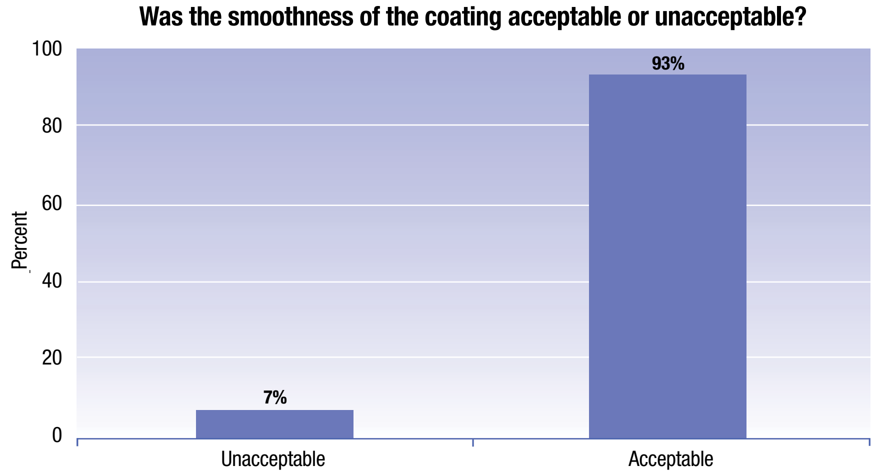


Figure 25. 93% of evaluators rated the smoothness of Vanish™ XT Extended Contact Varnish as Acceptable.

INSTRUCTIONS FOR USE

Refer to packaging of Vanish™ XT Extended Contact Varnish for instructions for use.

Storage and Use

Refer to packaging of Vanish™ XT Extended Contact Varnish for instructions for use.

Warranty

Refer to packaging of Vanish™ XT Extended Contact Varnish for instructions for use.

Limitation of Liability

Refer to packaging of Vanish™ XT Extended Contact Varnish for instructions for use.

QUESTIONS AND ANSWERS

Q. Can Vanish™ XT Extended Contact Varnish be used as a full mouth treatment?

A. Vanish XT varnish is designed for site-specific applications.

Q. Can Vanish XT varnish be removed from the tooth surface?

A. If necessary, the coating can be removed with the use of a coarse prophy paste or pumice.

Q. How thick should the coating of Vanish XT varnish be applied?

A. You need only apply a thin layer (1/2mm or less) of Vanish XT varnish to the tooth surface.

Q. Why is etching required for enamel applications, but not for dentin applications?

A. Vanish XT varnish has excellent adhesion to dentin without the need for a separate etching step. Etching the uncut enamel surface with phosphoric acid gel is required for bonding Vanish XT varnish; the etching process creates microtexture and greatly increases the surface area available for bonding, which enables a micromechanical bonding mechanism in addition to the chemical bond.

Q. How many teeth can be covered from one click of the Clicker™ Dispenser?

A. Depending on the type and size of the application, the number of teeth that can be covered with one click of the Vanish XT varnish Clicker dispenser is anywhere between 1 and 6.

Q. Will Vanish XT varnish interfere with the function of the orthodontic bracket?

A. No. Vanish XT varnish is compatible with orthodontic brackets and bonding systems.

Q. What type of fluoride does Vanish XT varnish contain and at which concentration? How does the fluoride content compare to a conventional 5% sodium fluoride varnish?

A. The patented resin modified glass ionomer chemistry in Vanish XT varnish provides a burst of fluoride released during the first several days after placement, and also long term sustained fluoride release over the life of the coating. The fluoride resides in fluoroaluminosilicate glass particles: reaction at the surface provides the immediate release, while the interior provides a reservoir of fluoride for sustained release. In contrast, conventional varnish with water-soluble sodium fluoride is designed to release much of its fluoride within the brief period, typically up to one day, before the bulk coating is worn away by brushing or food abrasion. Figure 6 shows the cumulative fluoride release data of Vanish XT varnish during the first 24 hours is statistically higher than Colgate® Duraphat®, a conventional sodium fluoride containing varnish. Vanish XT varnish also exhibits sustained long-term fluoride release as shown in Figure 7.

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