Profisil® Fluoride Varnish
Scanning Electron Microscopy (SEM) Study

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PURPOSE

Fluoride varnish has been known to effectively treat dentinal hypersensitivity by initially depositing sodium fluoride crystals into open tubules. These sodium fluoride crystals eventually convert to an insoluble calcium fluoride precipitate and block further stimulation of the fluid filled tubule. The activity of fluoride varnish formulas are validated by evidence of occlusion of dentinal tubules providing dentinal tubular occlusion.

The purpose of this in-vitro study was to evaluate the deposition of **Profisil**® Fluoride Varnish and a predicate device on mineralized tooth tissues and into exposed dentin tubules. As a predicate device two leading competitor product versions of sodium fluoride varnishes were drawn into consideration.

DENTIN OCCLUSION EXPERIMENT

Methods and Materials:

Bovine teeth were selected for observation of the occlusal effect post application of sodium fluoride varnishes. For each of three experimental conditions, three bovine teeth were cleaned using flour pumice and a rubber cup using a low-speed dental handpiece. After ultrasonic cleaning the teeth were prepared by exposing the tooth structure below the cemento-enamel junction to a phosphoric acid conditioning using 36% phosphoric acid etchant gel for 30 seconds. This exposed the opening of the dentinal tubules. 9 specimens were then organized into the following experimental groups:

(1) dentin surface treated with **Profisil**® Fluoride Varnish,

(2) dentin surface coated with leading competitor products and

(3) negative control sample of dentin surface without varnish treatment.

The treated tooth specimens were soaked in artificial saliva for 24 hours. Following the artificial saliva exposure, the samples were rinsed in nanopure water and dried. Samples were then cross sectioned by scoring and breaking across the varnish/tubule interface to expose in cross section the penetration of the varnish components into the dentinal tubules. The specimens were coated with gold/Pd and scanning electron micrographs were obtained.

In this section we note that the acceptance of comparability between the two leading competitor products is given, which is due to the chemical equality of both compositions as depicted in the following table.

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Table 1. Comparison of two leading competitor products and Profilsil® Fluoride Varnish

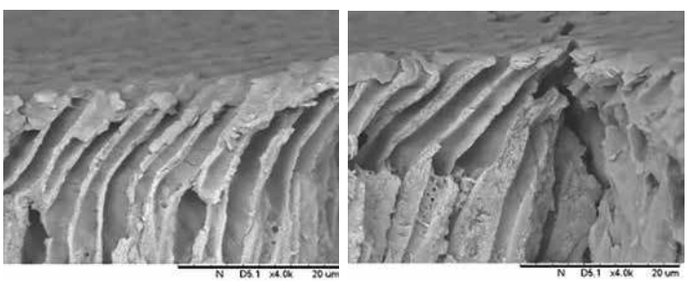
Basic formulation	Leading Competitor Product 1	Leading Competitor Product 2	Profilsil® Varnish	Comment
Encapsulant	Colophony	Pentaerythritol glycerol ester of colophony resin	Dimethicone	both competitor products use colophony
Solvent	Ethyl alcohol	n-Hexane, Ethyl alcohol	None	**Profisil**® does not contain any solvents
Flavor	Yes (e.g., bubblegum)	yes (e.g., cherry)	yes (e.g., Menthol)	comparable
Flavor enhancer	No information available	Trade Secret	Sucralose	comparable
Fluoride Source	5% Sodium fluoride	5% Sodium fluoride	5% Sodium fluoride	identical

As shown, both competitor products enclosed possess an analogous formulation structure, e.g., 5% sodium fluoride, a colophony resin, Ethyl alcohol as a solvent, a thickening agent, flavor, etc., which supports the determination of device equivalence.

The competitor products are equivalent on many levels. As noted in the formulation description they employ similar ingredients to carry sodium fluoride to the tooth surface. Both devices work by the deposition of calcium fluoride on the tooth surface which then acts as a mechanical barrier by precipitation into the dentinal tubules thereby reducing tooth sensitivity. The main difference between the competitor products is the incorporation of the whitening agent – tricalcium phosphate – that as a cosmetic adjunct does not participate in the mechanism of action for desensitization. Both competitor products act in an equivalent manner by using a colophony carrier for sodium fluoride.

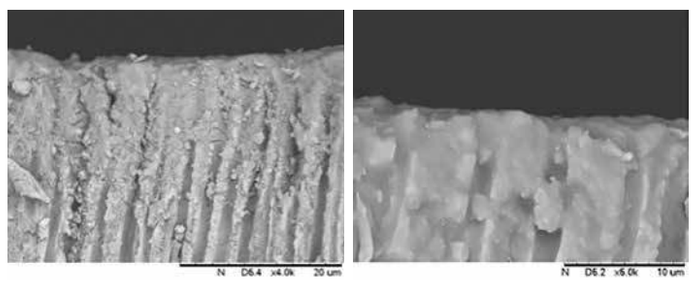
RESULTS-SCANNING ELECTRON MICROSCOPY IMAGING FOR DENTIN:

Control dentin micrographs



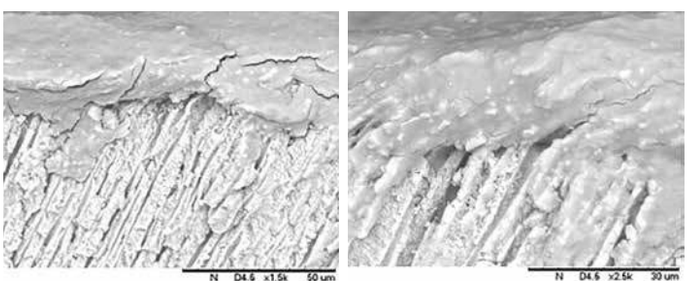
Dentin control surface in cross-section after exposure to artificial saliva. The surface was cleaned and acid conditioned.

Profisil® dentin micrographs



Profisil® Fluoride Varnish treated surface in cross-section. At 4000X magnification (left) penetration of varnish is seen up to 20 microns into the tubules. At 6000 X magnification (right) demonstrates the full tubular occlusion.

Dentin micrographs of competitor product



Competitor product treated surface in cross-section. Similar to **Profisil**® Fluoride Varnish the tubules have been occluded.

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CONCLUSION:

All varnish treated teeth (**Profisil**® Fluoride Varnish and competitor products) demonstrated occlusion of the previously patent dentin tubules. The negative control specimen showed no subsequent occlusion as expected. The SEM micrographs of both treated specimens showed an agglomeration of carrier material (dimethicone for **Profisil**® Fluoride Varnish, rosin for both competitor products) plugging the tubules to a depth of up 20 microns.

ENAMEL DEPOSITION EXPERIMENT

Methods and Materials:

Bovine teeth were selected for observation of the surface effect post application of sodium fluoride varnishes. For each of three experimental conditions, three bovine teeth were cleaned using flour pumice and a rubber cup using a low-speed dental handpiece. After ultrasonic cleaning the 9 specimens were then organized into the following experimental groups:

(1) enamel surface treated with **Profisil**® Fluoride Varnish,

(2) enamel surface coated with competitor product and

(3) negative control sample of enamel surface cleaned and without Varnish treatment.

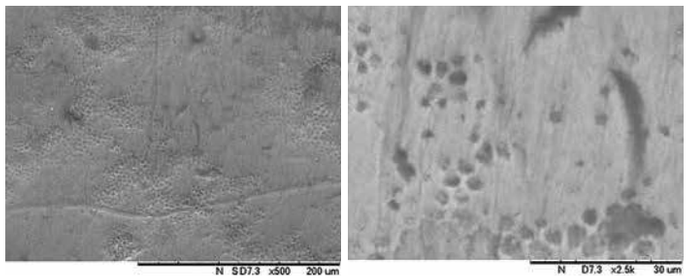
The treated tooth specimens were soaked in artificial saliva for 24 hours. Following the artificial saliva exposure, the samples were rinsed in nanopure water and dried.

To remove the competitor product, the teeth were soaked in ethanol to dissolve the rosin. To remove the **Profisil**® Fluoride Varnish, samples were soaked in hexane to remove the dimethicone carrier. No further treatment was required for the untreated sample except for rinsing off the artificial saliva with de-ionized water. The teeth specimens were dried and then sputter coated with gold/Pd.

The specimens were imaged by scanning electron microscopy.

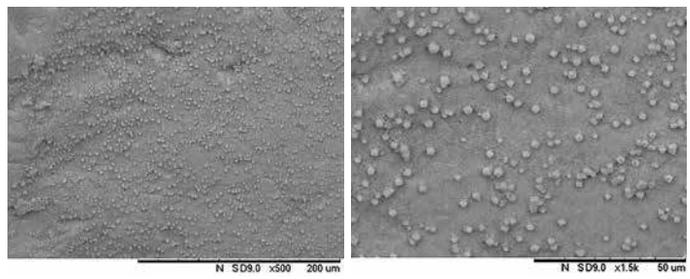
RESULTS-SCANNING ELECTRON MICROSCOPY IMAGING FOR ENAMEL:

Control enamel micrographs

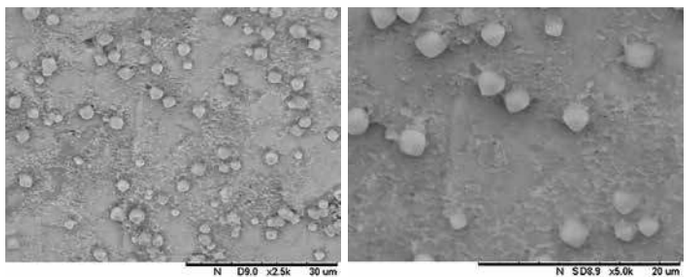


Control surface after exposure to artificial saliva.

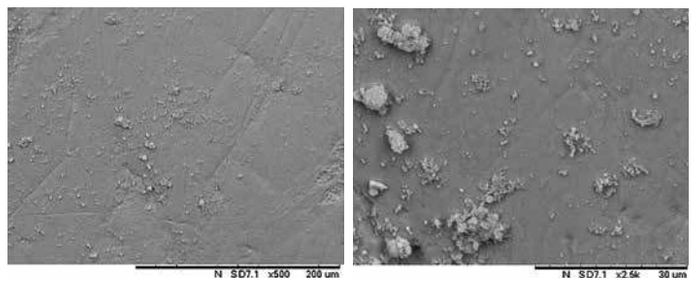
Profisil® enamel micrographs



competitor product enamel micrographs



The multiple magnifications show a uniform deposition of particulates over the surface compared to the control specimens.



The competitor product shows the deposition of particulate over the surface compared to the control specimens.

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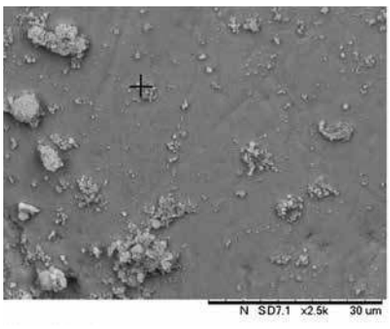
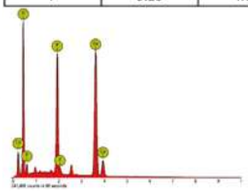
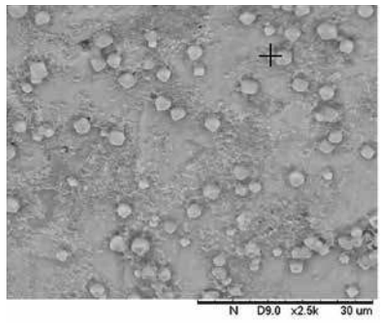
The SEM images are representative of the total surface area and the total cross-sectional area evaluated in the specimens studied. The cross-sectional images reveal a linear area of approximately 40 microns with the higher magnifications showing a 20-micron linear area to provide more morphological detail of the crystal precipitates of calcium fluoride. The penetration depth of the crystal deposition extends about 20 microns into the exposed dentinal tubule. The identity of the crystals is confirmed by the EDX study described. The surface area SEM at 500 X covers an area of approximately 60 mm2-a much larger area than the cross section showing the even distribution of calcium fluoride distribution across that larger area on the test specimen. Standard SEM practice is to evaluate the entire specimen and present representative images of the total liner or surface area of interest. The image evidence at the magnifications provided first show the robust and even precipitation distribution across the target surface (lower magnification) and at higher magnification in cross section showing the coating and penetration into the dentinal tubules confirming the mechanism of action. These cross -sectional representative images must be at higher magnification and thus cover a small linear area to show the morphology of the crystal deposits. The two views in combination provide confirmation of dentinal tubule occlusion across a wide and deep area in the test specimens.

RESULTS- ENERGY DISPERSIVE SPECTROSCOPY

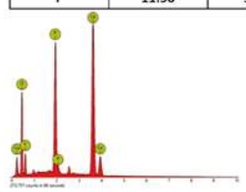


Element Symbol	Atomic Conc.	Weight Conc.
O	69.75	52.38
Ca	15.35	28.87
P	9.72	14.13
F	5.18	4.62





Element Symbol	Atomic Conc.	Weight Conc.
O	54.25	37.11
Ca	21.53	36.90
P	12.32	16.32
F	11.90	9.67



EDX demonstrates fluoride precipitate on the surface of enamel as a result of both varnish applications.

CONCLUSION:

This Scanning Electron Microscope (SEM) study shows the **Profisil**® Fluoride Varnish effectively penetrates the exposed dentin surface and occludes the open porosity. This study was conducted using two leading competitor products as a positive control. When compared to the competitor products, the **Profisil**® Fluoride Varnish performed in an equivalent manner.

SEM/EDX observations of the enamel treated by both competitor products and **Profisil**® Fluoride Varnish show a deposition of calcium fluoride crystals throughout the exposed enamel surface.