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3M™ Clinpro™ 5000

1.1% Sodium Fluoride Anti-Cavity Toothpaste

Technical Product Profile

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Background

Teeth are naturally covered by biofilm. Some bacteria contained in dental biofilm, once attached to the tooth, produce acids that dissolve tooth enamel and can ultimately lead to tooth decay.[1]

Demineralization occurs when the building blocks of teeth—calcium and phosphate—are dissolved by acid.[2] The process of demineralization may at first go unnoticed but will eventually result in a "white spot lesion." A white spot lesion is the first visible sign of demineralization and is considered one of the first stages of tooth decay.[3]

Saliva serves as the body's natural defense against tooth decay by providing both physical and metabolic protective mechanisms.

Saliva protects the tooth by clearing debris and acids from the tooth surface and by buffering acids produced in the mouth.[4] Saliva naturally contains calcium and phosphate that replace the minerals dissolved from teeth during the demineralization process.[2]

Saliva is also a carrier of fluoride.[2] Fluoride, calcium and phosphate come together on the tooth surface to form fluorapatite in a process called remineralization. Tooth surfaces made up of fluorapatite are harder and more resistant to acid than naturally occurring tooth surfaces, which are made of hydroxyapatite.[5]

The amount of naturally occurring fluoride in saliva is quite low. The scientifically proven beneficial effects of fluoride have prompted the addition of fluoride to drinking water, toothpastes, rinses, gels and other topically applied products.

Topical application of fluoride can raise the concentration of fluoride in saliva up to a thousandfold.[6]

Dental decay rates have decreased dramatically in many parts of the world over the past 60 years due to community water fluoridation, increased oral hygiene awareness and the use of fluoride-containing toothpastes. Fluoride delivery through community water fluoridation and through fluoridated toothpaste has been shown to be a cost-effective public health measure for preventing tooth decay.[7]

The amount of fluoride in toothpaste in the United States ranges from slightly less than 850 ppm to 5000 ppm. Fluoride toothpaste with a concentration of 1500 ppm or less is commonly sold to consumers through retail locations such as drugstores. Toothpaste with more than 1500 ppm fluoride is available only through professional application in the dental office or on a prescription basis.

Fluoride has been shown to reduce the incidence of caries.[8] Studies have shown that higher concentrations of sodium fluoride in toothpaste deliver statistically significantly greater anticaries efficacy.[9] Over-the-counter toothpastes typically contain 1100 ppm fluoride ion. 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste contains 5000 ppm fluoride ion, more than 4 times the amount in regular toothpaste. Large-scale clinical trials have demonstrated that higher concentrations of sodium fluoride in toothpaste deliver greater anticaries benefits.[10] Higher concentrations of sodium fluoride in toothpaste have greater anticaries benefits on vulnerable root surfaces, as well.[9,10]

Clinpro 5000 toothpaste was developed specifically for patients who need the benefits of a higher-concentration fluoride toothpaste. This toothpaste can be applied to enamel and exposed dentin through daily toothbrushing. The product provides a high concentration of fluoride during brushing to help remineralize demineralized enamel and to aid in the prevention of tooth decay.

Summary of advantages

- Contains 1.1% NaF (5000 ppm)
- Can recharge fluoride-releasing dental materials with fluoride
- Protects against cavities and helps reverse white spot lesions
- Contains functionalized tri-calcium phosphate (fTCP)
- Cleans and whitens teeth with low abrasion
- Perfect for patients at moderate or high risk for caries
- One-step convenience improves patient compliance
- Proven through 10 years of clinical usage

Product Description

3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste (fTCP) with functionalized tri-calcium phosphate is a prescription-strength toothpaste that contains 5000 ppm fluoride and was the first toothpaste on the market to utilize an innovative, functionalized tri-calcium phosphate ingredient. The product is intended to be used once a day for patients 6 years and older in place of a conventional toothpaste, unless instructed otherwise by a dentist or physician, and can be applied to enamel and exposed dentin to help remineralize demineralized tooth structure and aid in the prevention of tooth decay. Clinpro 5000 toothpaste has a pH of 6.4 and adjusts to a pH of 7 during normal toothbrushing.

Indications

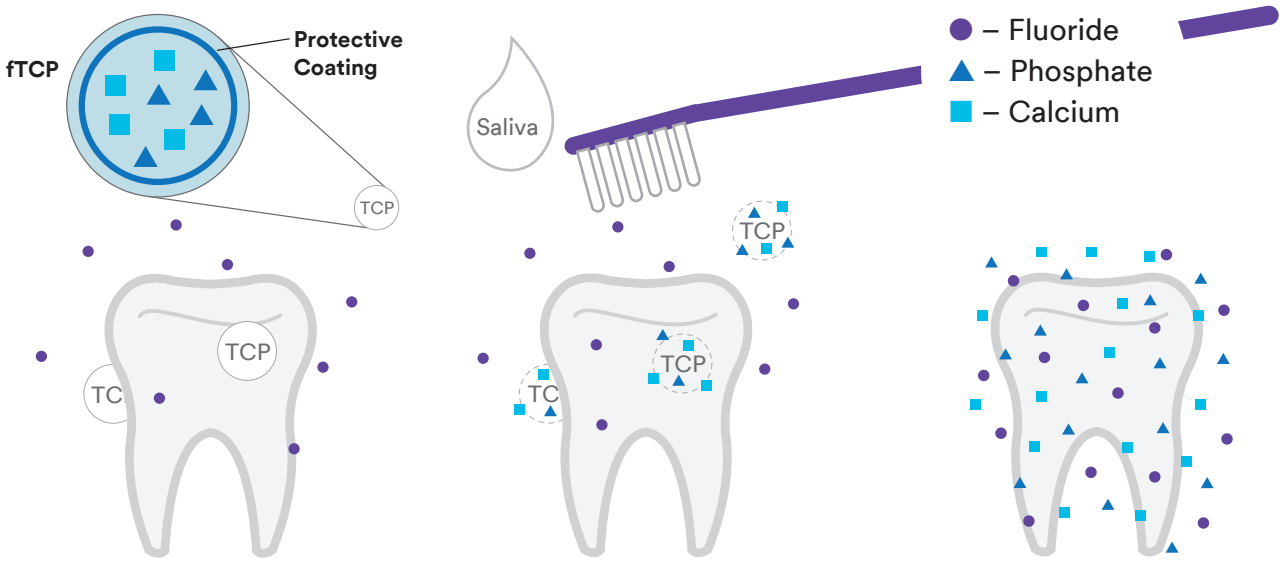
3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste is indicated for use as part of a professional program for the prevention and control of dental caries.

Composition

3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste contains 1.1% sodium fluoride and an innovative tri-calcium phosphate ingredient sold exclusively by 3M. Each gram of Clinpro 5000 toothpaste contains 5 mg of fluoride ion in a neutral pH base consisting of water, sorbitol, hydrated silica, glycerin, polyethylene-polypropylene glycol, flavor, polyethylene glycol, sodium lauryl sulfate, titanium dioxide, carboxymethyl cellulose, sodium saccharin and tri-calcium phosphate.

Functionalized Tri-calcium Phosphate

Clinpro 5000 toothpaste contains an innovative tri-calcium phosphate (fTCP) ingredient available exclusively from 3M. Calcium and phosphate in the form of fTCP are added to enhance the naturally occurring mineral content of saliva necessary for building strong teeth. The fTCP ingredient includes a protective coating on the minerals, which ensures the calcium and fluoride do not combine prematurely while in the tube. After Clinpro 5000 toothpaste is exposed to saliva, the protective coating dissolves, allowing the calcium and phosphate to be released together with fluoride ions. When released together, they have a better chance of combining to form strong tooth mineral.



1. **A protective coating around calcium and phosphate prevents early interactions with fluoride.**
2. **During brushing, saliva breaks down the coating.**
3. **Calcium and phosphate are released, making them available directly at the tooth surface along with fluoride.**

Directions for Use

Use once daily in place of conventional toothpaste, unless otherwise instructed by a physician or dentist. Apply a thin ribbon or pea-sized amount of 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste using a soft-bristled toothbrush and brush teeth for at least 2 minutes.

- After brushing, adults should expectorate. Avoid rinsing with water after use for added benefit.
- Children 6–16 years of age should expectorate and rinse mouth thoroughly with water.
- Do not use in children younger than 6 years of age unless recommended by a physician or dentist.

For full prescribing information and patient information, refer to package insert, which is available at www.3M.com.

Evaluations and Studies

Fluoride Uptake

While the concentration of fluoride in toothpaste is important, the amount of fluoride that is delivered to demineralized tooth structure is equally, if not more, important. *In vitro* laboratory testing was conducted to determine the fluoridating efficiency of 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste compared to that of other fluoride-containing preparations.

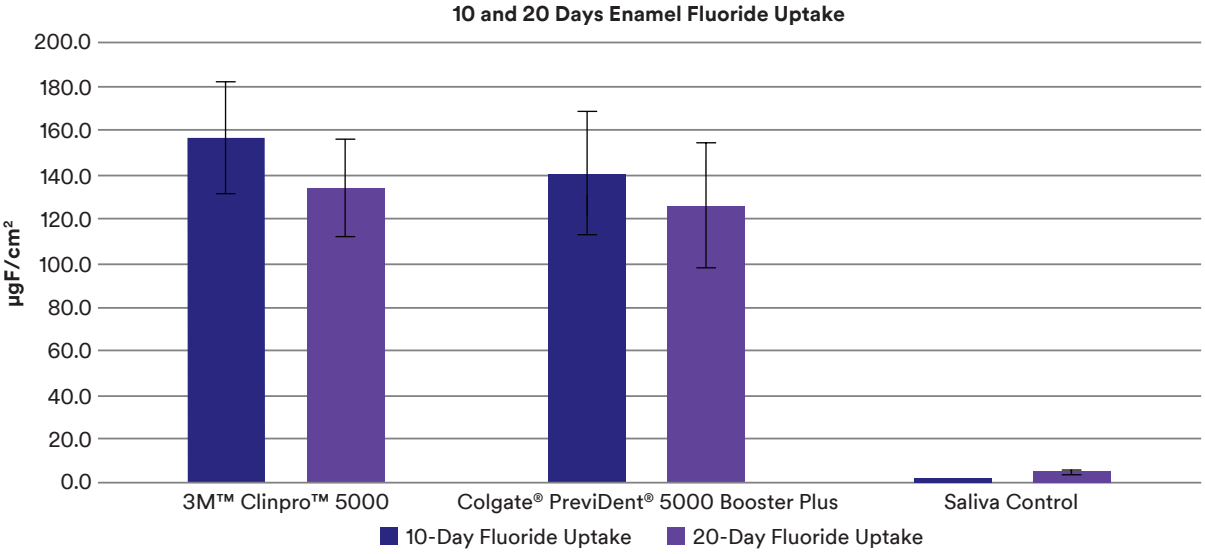
Methodology

Bovine teeth were cut, potted and polished. Samples were demineralized with a Carbopol®/lactic acid solution to form subsurface enamel lesions. Samples received four, 2-minute treatments of either Clinpro 5000 toothpaste, Colgate® PreviDent® 5000 Booster Plus or artificial saliva daily, followed by saliva wash for 1 hour. Samples received a 4-hour acid challenge daily between the first two and second two treatments, and sat in a saliva solution overnight. There was no rinsing after treatments.

A microdrill biopsy was taken to measure fluoride uptake into the enamel samples after 10 days and 20 days of treatment. The fluoride level after treatment was compared to the fluoride level before treatment to determine fluoride uptake.

Results

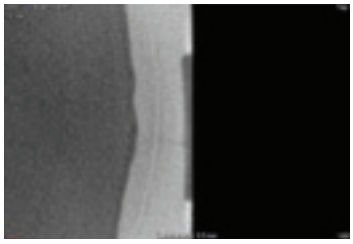
Clinpro 5000 toothpaste exhibited statistically significantly greater fluoride uptake than the saliva control, and equivalent fluoride uptake compared to Colgate® PreviDent® 5000 Booster Plus.



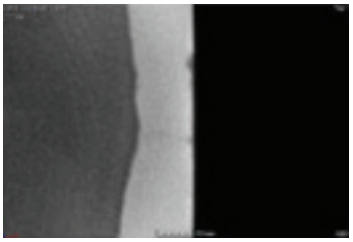
Source: 3M internal data

Remineralization

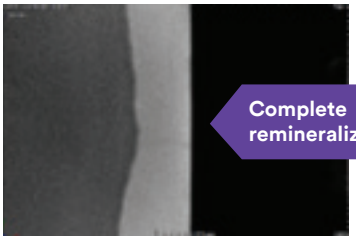
Remineralization is a natural process which is essential to repair and maintain strong tooth structure. *In vitro* laboratory testing was conducted to determine the remineralizing capabilities of 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste compared to that of other fluoride-containing preparations.



Baseline



10 days pH cycling



20 days pH cycling

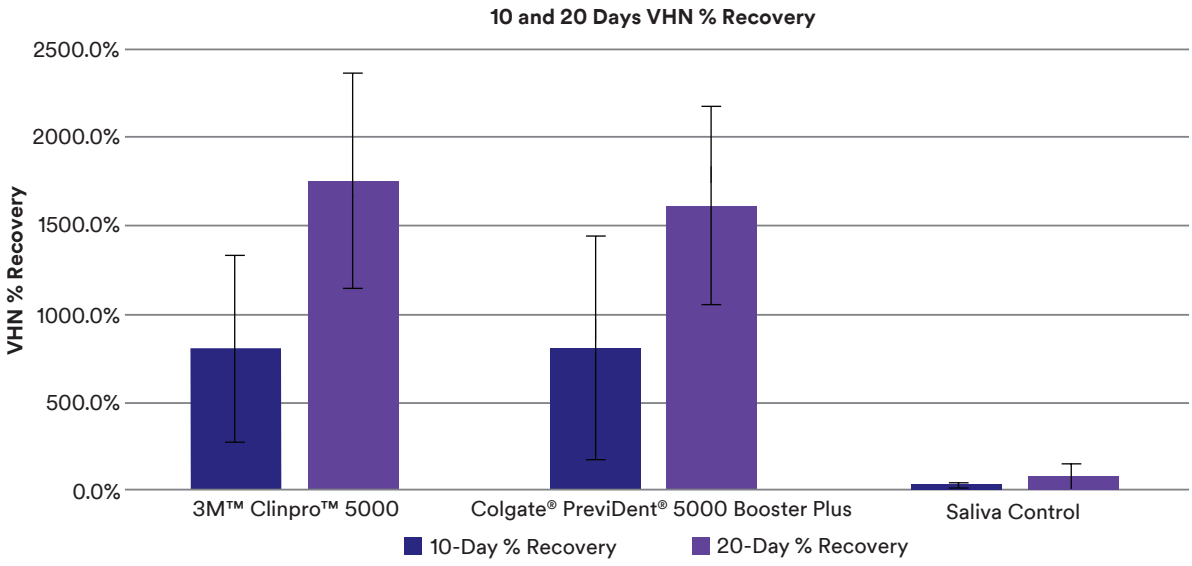
Methodology

Bovine teeth were cut, potted and polished. Samples were demineralized with a Carbopol®/lactic acid solution to form subsurface enamel lesions. Samples received four, 2-minute treatments of either Clinpro 5000 toothpaste, Colgate® PreviDent® 5000 Booster Plus or artificial saliva daily, followed by artificial saliva wash for 1 hour. Samples received a 4-hour acid challenge daily between the first two and second two treatments, and sat in an artificial saliva solution overnight. There was no rinsing after treatments.

Lesions with similar microhardness values were selected with a Buehler Micromet hardness tester. The change in surface microhardness was measured according to Vickers surface microhardness after 10 days and 20 days of toothpaste treatments. Specimens were scanned using a micro-computed tomography to visualize remineralization.

Results

Clinpro 5000 toothpaste exhibited statistically significantly greater remineralization than the saliva control and equivalent remineralization compared to Colgate® PreviDent® 5000 Booster Plus after 20 days of treatment.



Source: 3M internal data

Treatment of White Spot Lesions

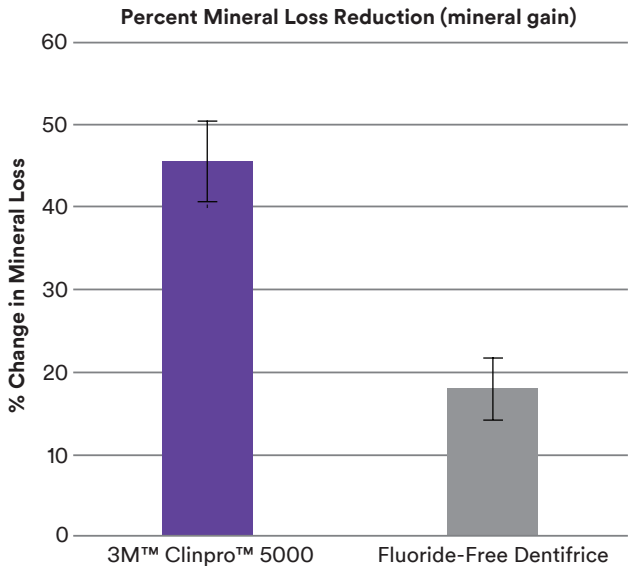
White spot lesions are an early sign of tooth decay that, if left untreated, will progress to frank caries lesions. Treatment of these demineralized areas with fluoride can stop progression and reverse the decay process through remineralization.[11]

Methodology

Demineralized enamel blocks and healthy blocks (cut from a group of 30 molars) were exposed in pairs (one demineralized, one sound) via an appliance worn by 30 adults in a crossover study lasting 28 days per phase. The pairs were exposed to dentifrices containing 5000 ppm fluoride with tri-calcium phosphate, and to a dentifrice with no fluoride at all. Lesion status was analyzed using surface microhardness and transverse microradiography.

Results

In this *in situ* clinical study, 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste significantly inhibited demineralization of sound enamel and significantly remineralized white spot lesions as represented by the amount of mineral gain by the lesioned enamel.[12]



Source: Amaechi, Ramalingam, Mensinkai, & Chedjieu

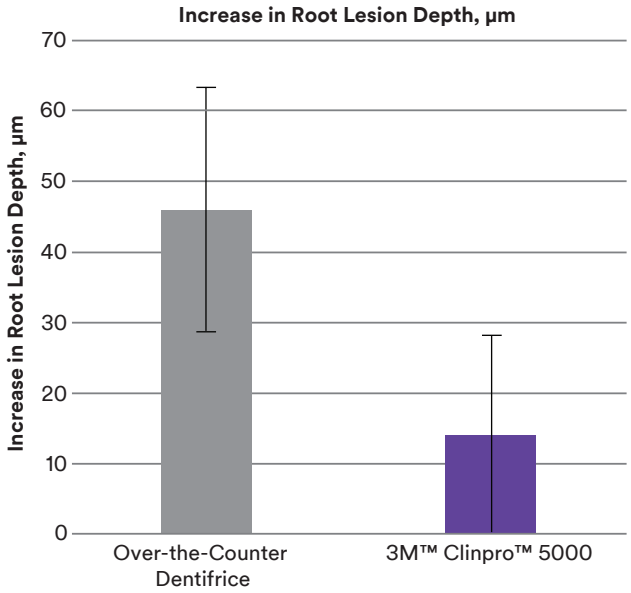
Root Caries

Root caries is decay on the root surface of the tooth. Root surfaces of teeth are composed of dentin, a much softer material than enamel. The caries process on the roots of teeth is similar to that of the enamel. However, dentin is less mineralized and softer than enamel and is therefore more vulnerable to decay. Fluoride-containing toothpastes, like 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste, are considered part of the primary protection from root caries and are also a viable treatment option for those with early stages of the disease process.[13]

Methodology

Twenty extracted, non-carious human tooth roots were painted, exposing a 1mm x 6mm area of root surface. The samples were suspended in a demineralizing solution to form initial root lesions. Each tooth was sectioned into samples, the lesion depth was measured using polarized light microscopy and each sample was randomly assigned to a treatment group: Clinpro 5000 toothpaste (5000 ppm), or an over-the-counter dentifrice (1100 ppm). To simulate daily biological cycling, all root surfaces underwent exposure to demineralizing and remineralizing solutions, as follows:

1. Acetic acid solution (pH 4.3): mimicking the decrease in oral pH that occurs following food and beverage consumption.
2. Artificial saliva: intermittent time between meals.
3. Brushing with toothpaste or professional application of fluoride product. Following cycling, the lesions were characterized using polarized light microscopy.



Results

Clinpro 5000 toothpaste provided greater protection against root lesion progression than an over-the-counter toothpaste.[14]

The American Dental Association has published evidence-based guidelines indicating that noncavitated and cavitated carious root lesions treated with 5000 ppm fluoride (1.1% NaF) toothpaste or gel had a 3 times greater chance of arrest or reversal of the lesion than no treatment at all.[15]

Source: Schiltz, Kolker, Wefel, Hogan, Harless, Qian, & Shimek

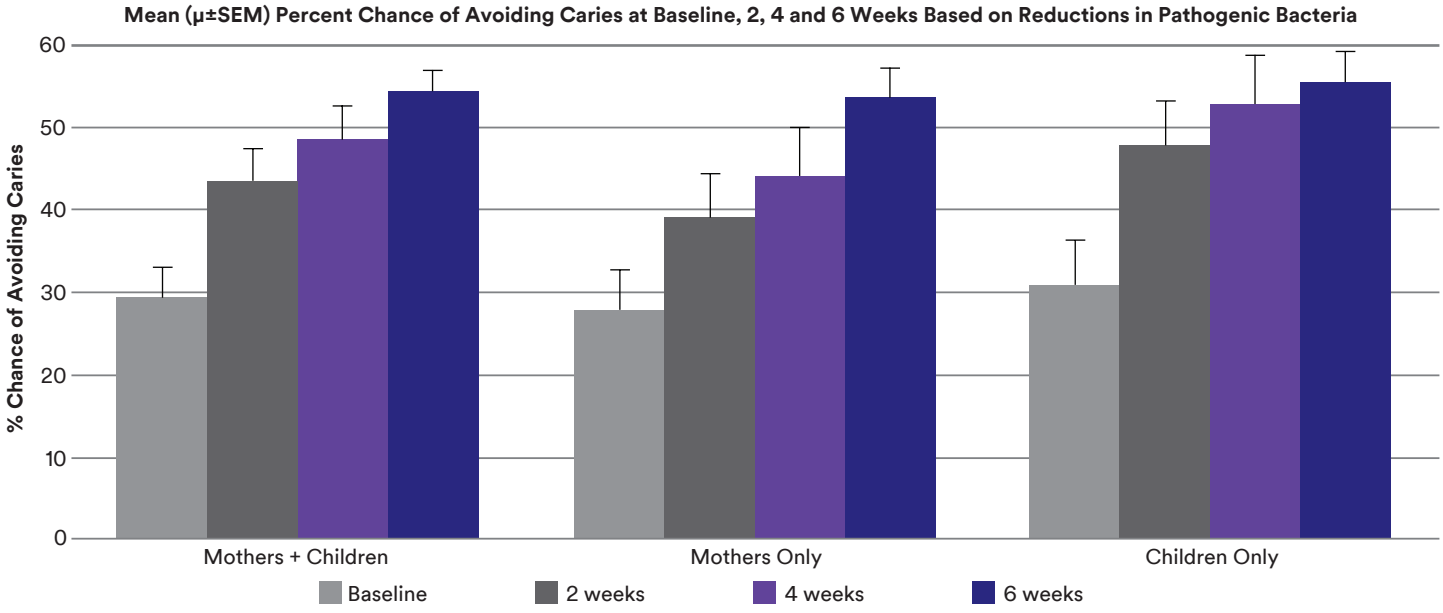
Reducing Caries Risk

Methodology

Thirty-four participants (17 mothers and their teenage children) enrolled in this 6-week clinical study where they were to brush with 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste. Buffer capacity, lactobacilli and mutans streptococci were clinically assessed at baseline, 2, 4 and 6 weeks. Based on these data, seven caries-related variables were collected and inputted into Cariogram software as a means of calculating the chance of avoiding caries.

Results

The use of Clinpro 5000 toothpaste resulted in a statistically significant modification to the caries-risk profiles, and this was largely due to the significant reductions in lactobacilli and mutans streptococci pathogen counts. When these data were analyzed, relative to baseline risk, the mothers and their teenage children demonstrated significantly lower caries risk beginning at 2 weeks and extending through the 6 weeks.[16]



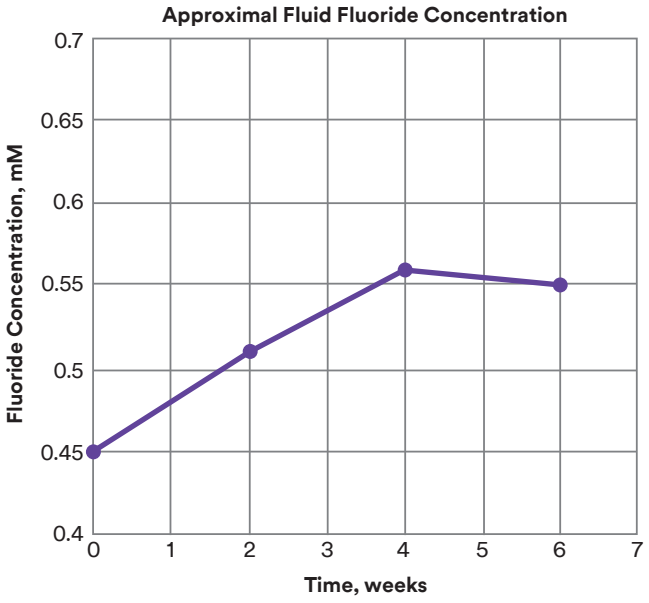
Source: Mannaa, Campus, Carlén, & Lingström

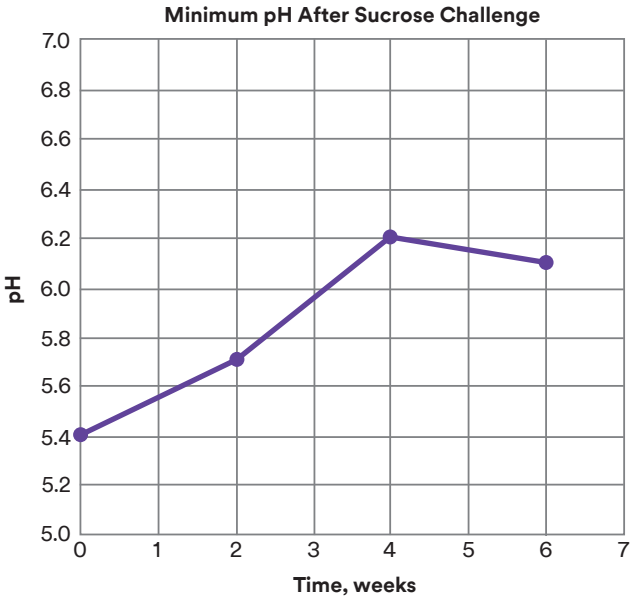
Methodology

Twenty-six participants completed a 6-week clinical trial in which they were assessed on four visits, 2 weeks apart. Sampling of approximal fluid for fluoride analysis and approximal plaque for organic acid analysis was performed. Chairside tests were performed to register the lactic acid production rate on the tongue, the pH of approximal plaque and salivary buffer capacity and counts of cariogenic microorganisms.

Results

Use of Clinpro 5000 toothpaste for 6 weeks significantly increased the approximal fluid fluoride concentration, decreased the lactic acid production rate, reduced the pH drop and increased the minimum pH after a sucrose challenge.[17]





Source: Mannaa, Carlén, Zaura, Buijs, Bukhary, & Lingström

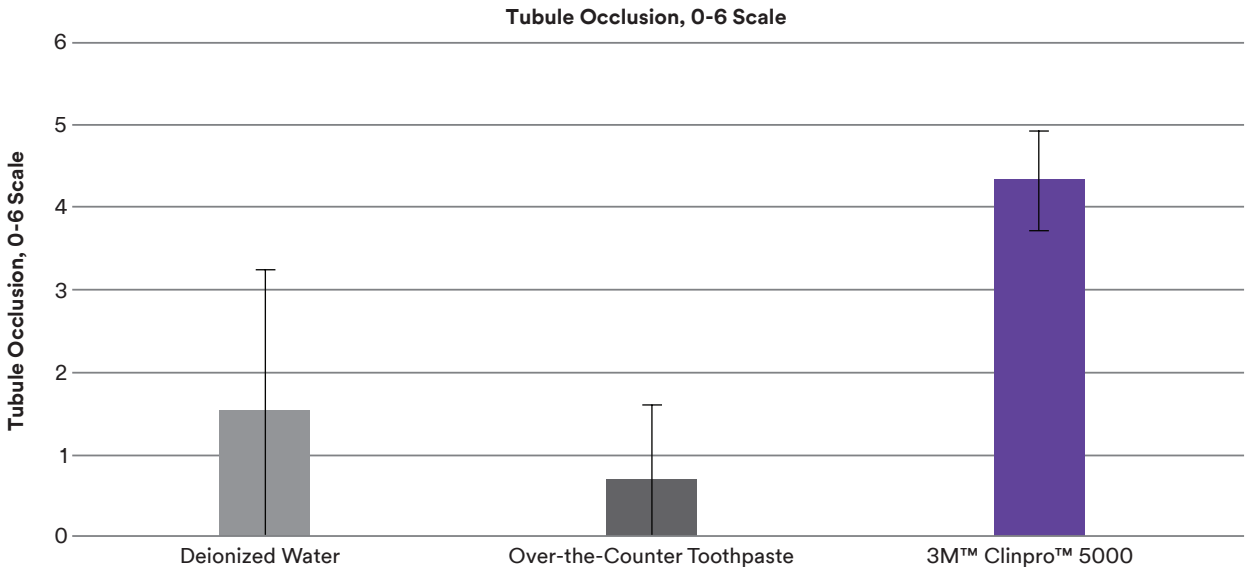
Dentin Tubule Occlusion

Methodology

Bovine dentin samples with lesions were subjected to pH cycling and toothpaste treatments for 7 days. The degree of dentin tubule occlusion was scored based on images taken with a microscope.

Results

The tubule occlusion of 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste was higher than water and an over-the-counter toothpaste. Regular use of Clinpro 5000 toothpaste occludes exposed dentin tubules.[18]



Source: Mackey, Karlinsey, Gidley, Stookey, & Pfarrer

Fluoride Recharge

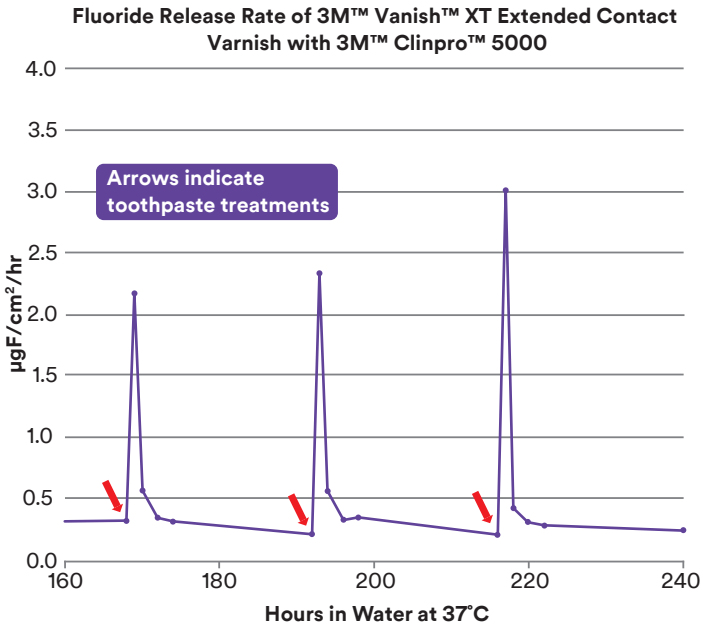
Many dental restorative and sealant materials contain and release fluoride. This is considered to be an advantage in protecting against a recurrence of caries after dental treatment is complete. Fluoride release from such materials is initially high but declines naturally with time.[19]

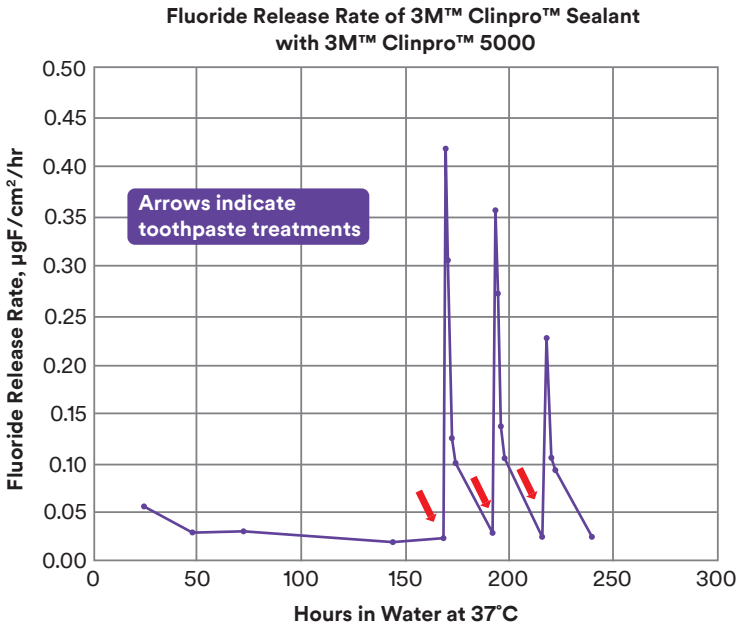
Methodology

Fluoride release of light-cured dental materials was measured before and after treatments with 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste. Fluoride release was measured at 1, 2, 3, 6 and 7 days after immersion using a fluoride selective electrode. All samples were depleted of their "initial burst" of fluoride, after which samples entered a steady-state release phase. Toothpaste treatments (1:3 paste:H2O, 2 min) were applied at 7, 8 and 9 days and measured at 1, 2, 4, 6 and 24 hours after each treatment.

Results

In vitro testing demonstrates that fluoride-releasing materials can absorb and continue to rerelease fluoride after brushing with Clinpro 5000 toothpaste. This ability to recharge dental materials with fluoride has been recognized in glass ionomers and resin-based sealant material.





Source: 3M internal data

Extrinsic Stain Removal

The cleaning efficiency of toothpaste is determined using the Pellicle Cleaning Ratio (PCR) test.

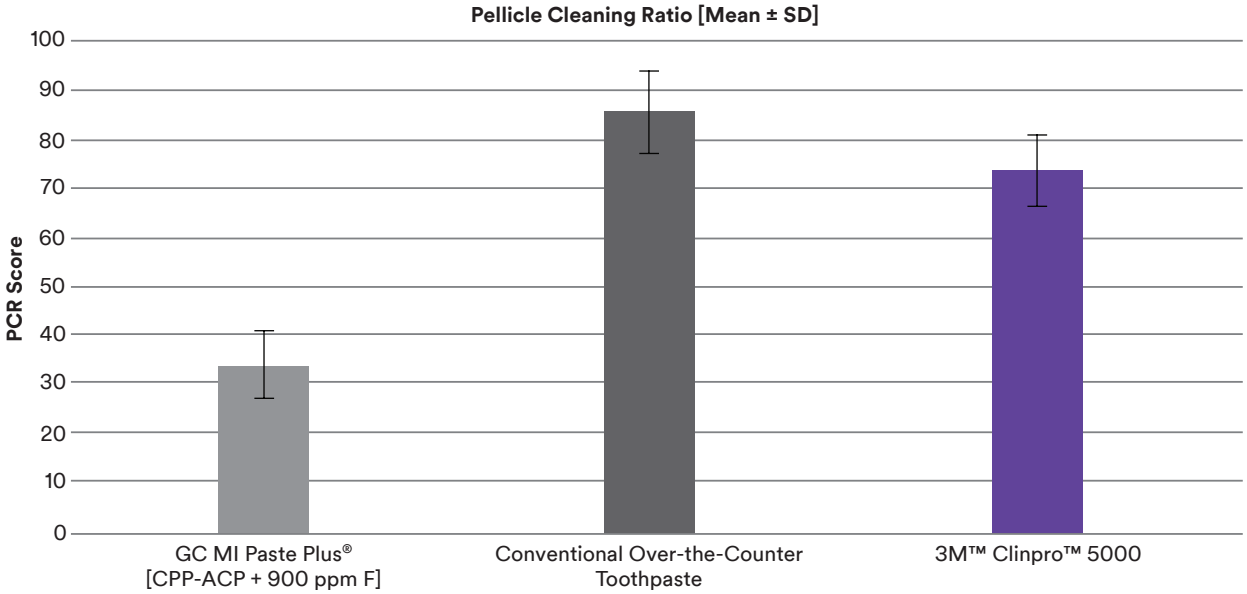
This *in vitro* test evaluates a toothpaste formulation's ability to remove stained pellicle compared to that of the American Dental Association (ADA) reference standard, calcium pyrophosphate. Higher PCR scores are reflective of better cleaning and whitening. In this experiment, over-the-counter toothpastes typically exhibit PCR scores between 65 and 115.22.[20]

Methodology

Specimens of enamel were prepared from bovine teeth. The specimens were stained by alternatively submerging and air-drying in a solution of soy broth, tea, coffee, mucin and *Sarcina lutea* for a period of 4 days. Following staining, the color of each specimen was measured using a spectrophotometer. Stained specimens were placed on a V-8 cross-brushing machine equipped with soft-bristled toothbrushes. One hundred fifty grams of force was applied to the toothbrushes. Specimens were brushed with slurries (25 grams of fluoride-containing preparation and 40 grams of deionized water) for a total of 800 strokes. One slurry contained 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste, while the others contained GC MI Paste Plus® or a conventional 1100 ppm fluoride toothpaste. Following brushing, the color of each specimen was measured. The change in color observed for each slurry was compared to that observed for the ADA reference standard of calcium pyrophosphate to determine the PCR score.

Results

Clinpro 5000 toothpaste exhibited a PCR value of 73.9, which indicates effective stain removal. This value is statistically greater than the 33.8 PCR value achieved with GC MI Paste Plus®. Clinpro 5000 toothpaste effectively cleans and whitens teeth.



Source: 3M internal data

Abrasivity

Toothpaste needs to strike a balance between effective cleaning and abrasivity. Toothpastes that are highly abrasive can damage enamel and dentin over time. ISO 11609 Dentistry—Toothpastes—Requirements, Test Methods and Marking contains an abrasivity requirement and provides appropriate test methods for determining abrasivity. Two tests, relative dentin abrasion (RDA) and relative enamel abrasion (REA), were performed to determine if the abrasive system used in this formulation is safe for twice-daily, unsupervised toothbrushing.

Methodology

The RDA and REA tests are similar. Irradiated dentin or enamel was brushed with slurries (25 grams of fluoride-containing preparation with 40 grams of deionized water). Abrasivity was reported relative to a reference standard abrasive, calcium pyrophosphate. When evaluating dentin, the test formulation must not exceed 2.5 times that of the reference standard abrasive (that is assigned a value of 100); when evaluating enamel, the test formulation must not exceed 4 times that of the reference standard abrasive (that is assigned a value of 10).

Because dentin is considered approximately tenfold more susceptible to abrasion than enamel (the reason for the assignment of 100 and 10 for the reference standard), dentin abrasivity is often viewed as a more appropriate measure of abrasivity to ensure the preparation is not overly aggressive.

Results

The RDA value observed for 3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste was 62.15, well under the limit of 250. This indicates that Clinpro 5000 toothpaste is gentle to dentin. The REA value for Clinpro 5000 toothpaste was 3.49, well under the limit of 40. Clinpro 5000 toothpaste provides gentle, effective cleaning of enamel and dentin.

Source: 3M internal data

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3M™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste

BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE

Clinpro 5000 Anti-Cavity Toothpaste is indicated for use as part of a professional program for the prevention and control of dental caries.

DOSAGE AND ADMINISTRATION

- Use once daily in place of conventional toothpaste unless instructed otherwise by a physician or dentist.
- Apply a thin ribbon or pea-sized amount of Clinpro 5000 Anti-Cavity Toothpaste using a soft-bristled toothbrush, and brush teeth for at least two minutes.
- After brushing, adults should expectorate. Children 6 to 16 years of age should expectorate and rinse mouth thoroughly with water.
- Follow these instructions or use as directed by a dental professional.

DOSAGE FORMS AND STRENGTHS

White toothpaste containing 1.1% sodium fluoride

CONTRAINDICATIONS

Do not use in children under 6 years of age unless recommended by a dentist or physician.

WARNINGS AND PRECAUTIONS

- DO NOT SWALLOW. If more than a pea-sized amount of Clinpro 5000 Anti-Cavity Toothpaste is swallowed, contact a medical or dental professional or a poison control center.
- Keep out of reach of children under 6 years of age.
- Repeated ingestion of high levels of fluoride may cause dental fluorosis. For this reason, use in children with developing dentition requires special supervision to prevent swallowing. Prescribing dentists and physicians should consider risk of fluorosis when prescribing for use in children less than 6 years of age.

ADVERSE REACTIONS

Allergic reactions and other idiosyncrasies have been rarely reported.

USE IN SPECIFIC POPULATIONS

Pregnancy

Prescribing physicians and dentists should consider total fluoride exposure (dental care plus food, water and other sources) when prescribing the product for use in pregnant women or women who may become pregnant.

Nursing Mothers

Prescribing physicians and dentists should consider total fluoride exposure (dental care plus food, water and other sources) when prescribing the product for use in women who are nursing.

Pediatric Use

The primary adverse effects of fluoride are fluorosis of dental enamel and of the skeleton; these effects occur at exposures below those associated with other adverse health effects. The population most at risk for dental fluorosis is children during the period of tooth formation, i.e., from birth to 8 years of age. For this population, the Institute of Medicine (IOM) established Fluoride Upper Limits of intake based on the risk of dental fluorosis. In populations with permanent dentition, skeletal fluorosis is the greatest risk from excessive fluoride. For this population, the IOM established Fluoride Upper Limits based on the risk of skeletal fluorosis.

Population	IOM Fluoride Upper Limit
Infants 0–6 months old	0.7 mg/day
Infants 7–12 months old	0.9 mg/day
Children 1–3 years old	1.3 mg/day
Children 4–8 years old	2.2 mg/day
Children > 8 years old	10 mg/day

Prescribing physicians and dentists should consider total fluoride exposure (dental care plus food, water and other sources) when prescribing product for use in children.

Geriatric Use

No studies of Clinpro 5000 Anti-Cavity Toothpaste have been conducted to determine whether subjects aged 65 and over respond differently from younger subjects.

OVERDOSAGE

Ingestion of large amounts of fluoride may result in abdominal pain, stomach upset, nausea, vomiting and diarrhea. These symptoms may occur at overdosages of 5mg/kg of body weight. Fluoride doses of 16mg/kg have been fatal.

Treatment Recommendations for Overdose of Clinpro 5000 Anti-Cavity Toothpaste

Ingested fluoride dose	Amount for 10kg (22-pound) child*	Recommended action to take
Less than 5 mg/kg	This equals less than ½ ounce (or less than 3 teaspoons).	Do not induce vomiting. Give 1–2 glasses of milk and observe for symptoms of stomach upset. If symptoms persist more than a few hours, seek medical attention or contact a poison control center.
5 mg/kg or more	This equals about ½ ounce (about 1 tablespoon) or more.	Do not induce vomiting. Give 1–2 glasses of milk and seek medical attention or contact a poison control center.
15 mg/kg	This equals 1 ounce or ¼ of the tube.	Seek immediate medical attention. Do not induce vomiting. Give 1–2 glasses of milk.

*The amount to reach the fluoride dose will be proportionately larger with older children and adults.

A thin ribbon or pea-sized amount of Clinpro 5000 Anti-Cavity Toothpaste weighs approximately 0.3 grams and contains approximately 1.5 milligrams of fluoride ion. A 4-ounce tube contains 564 milligrams of fluoride ion.

DESCRIPTION

Clinpro 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste is a self-applied fluoride dentifrice for the prevention of dental caries. Each gram contains 5 milligrams of fluoride ion in a neutral pH base, consisting of water, sorbitol, hydrated silica, glycerin, polyethylene-polypropylene glycol, flavor, polyethylene glycol, sodium lauryl sulfate, titanium dioxide, carboxymethyl cellulose, sodium saccharin and tri-calcium phosphate.

Manufactured for: 3M ESPE
Dental Products
St. Paul, MN 55144 USA
Revision date: 01/11/2012
Rx Only

This is a summary of the prescribing information. For complete prescribing information, please visit www.3MESPE.com.

www.3M.com/PreventiveCare

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