Clinpro™ Tooth Crème
0.21% w/w Sodium Fluoride Anti-Cavity Paste with Tri-Calcium Phosphate
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INTRODUCTION

Caries Development
Teeth are naturally covered by dental plaque that contains bacteria. Some of the bacteria, including mutans streptococci and lactobacilli, produce acids when they metabolize fermentable carbohydrates such as glucose, sucrose, fructose, or cooked starch. The acids produced by this metabolism enter into the pores of sound tooth enamel or exposed dentin and dissolve minerals in the tooth structure. This causes a loss of calcium and phosphate from the tooth, resulting in demineralization.1-4

Plaque bacteria + Fermentable carbohydrates => Acids
Acids + Tooth enamel and dentin => Demineralization

Demineralization is first visible as a “white spot lesion” on the surface of the tooth enamel. Left untreated, this process can continue, eventually leading to cavitation.

Caries Prevention
Saliva serves as the body’s natural defense against tooth decay by both physical and chemical means. Saliva protects the tooth by clearing carbohydrates and acids from the tooth surface and buffering the acids generated by carbohydrate metabolism. Saliva contains minerals such as calcium and phosphate that replace the minerals dissolved from the tooth during demineralization.5

Saliva is also a carrier of fluoride. Fluoride in sufficient quantities combines with the demineralized hydroxyapatite of tooth structure to form fluorapatite in a process known as remineralization. Fluorapatite is more resistant to acid challenge than naturally occurring hydroxyapatite. This minimizes the formation of dental caries.

Unfortunately, the amount of fluoride in saliva is low. Fluoride in whole saliva is approximately 0.32 μmol/l in areas with low fluoride concentration in drinking water.6 Because of the known beneficial effects of fluoride on teeth, fluoride is added to drinking water and to toothpastes, rinses, gels and other topically-applied products. Topical application of fluoride can raise the concentration of fluoride in saliva up to 1000-fold.7

Caries rates have decreased dramatically in many parts of the world over the past 40 years due to community water fluoridation, increased oral hygiene awareness and the use of fluoride-containing toothpaste.8-12 Fluoride delivered through community water fluoridation and fluoridated toothpaste has been shown to be a cost-effective public health measure for preventing tooth decay.11,12

Clinpro™ Tooth Crème 0.21% w/w Sodium Fluoride Anti-Cavity Paste was developed specifically for patients who need the benefits of a professionally-dispensed fluoride-containing preparation. This fluoride-containing creme can be applied to enamel and exposed dentin through daily tooth brushing. The product provides fluoride during brushing to help remineralize demineralized enamel and to aid in the prevention of tooth decay.
PRODUCT DESCRIPTION
Clinpro™ Tooth Crème 0.21% w/w Sodium Fluoride Anti-Cavity Paste is a white creme that contains 950 ppm fluoride and an innovative tri-calcium phosphate ingredient with a vanilla mint flavor. The product is intended to be used once daily in place of conventional toothpaste, unless instructed otherwise by a physician or dentist.

Clinpro Tooth Crème is packaged in a 113g tube.

INDICATIONS
Clinpro Tooth Crème is indicated for use as part of a professional program for the prevention and control of dental caries.

COMPOSITION
Clinpro Tooth Crème contains 0.21% w/w sodium fluoride and an innovative tri-calcium phosphate ingredient which is sold exclusively through 3M ESPE. Each gram of Clinpro Tooth Crème contains 0.95 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.

EVALUATIONS
Fluoride has been shown to reduce the incidence of caries.13 Clinpro Tooth Crème contains 950 ppm F- and has been shown to deliver fluoride, help strengthen enamel, and help reverse white spot lesions better than GC MI Paste Plus™.

Fluoride Uptake
While the concentration of fluoride in a preparation 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 Clinpro Tooth Crème compared to that of other fluoride-containing preparations.

Methodology
Enamel chips were prepared from bovine incisors. The tooth surfaces were ground flat and then polished. The indigenous fluoride level of each chip was determined. The chips were demineralized using a solution of 0.1M lactic acid and 0.2% carbopol. Following demineralization, the chips were treated for 30 minutes by soaking in a slurry of fluoride preparation and water. The fluoride preparations consisted of the following:

- Fluoride-free deionized water
- GC MI Paste Plus™ (900 ppm F-)
- Clinpro Tooth Crème (950 ppm F-)

Following treatment, chips were re-analyzed using the same technique used to determine indigenous fluoride level. The fluoride level after treatment was compared to fluoride level before treatment to determine fluoride uptake.
Results
Clinpro Tooth Creme exhibited statistically significantly greater fluoride uptake than GC MI Paste Plus. This suggests that the anticaries potential of Clinpro Tooth Creme is greater than that of GC MI Paste Plus.

Fluoride Bioavailability
“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. An in vitro pH cycling experiment was conducted to assess the fluoridating and remineralizing efficiency of Clinpro Tooth Crème and GC MI Paste Plus. The pH cycling model is a widely-accepted and validated method to evaluate the anticaries potential of fluoride-containing formulations.

In this experiment, specimens were subjected to 20 days of pH cycling. The purpose of this in vitro laboratory experiment was to determine the ability of Clinpro Tooth Crème to:

- promote fluoride uptake
- promote remineralization

Methodology
Enamel specimens were cut from bovine incisors. Each specimen was soaked in a solution of 0.1M lactic acid and 0.2% carboxpol to produce artificial caries lesions. Baseline surface microhardness measurements were made. Eighteen specimens were then randomized to each of the following treatment groups:

- Fluoride-free deionized water
- GC MI Paste Plus (900 ppm F-)
- Clinpro Tooth Crème (950 ppm F-)

![Fluoride Uptake into Demineralized Enamel](source: 3M ESPE internal data)
Each group of specimens was subjected to 20 days of pH cycling with each day consisting of a series of soaking in demineralizing solution, artificial saliva and fluoride preparation treatments (a slurry of one part fluoride preparation and three parts water). A 1:3 dilution of the fluoride-containing preparation represents normal tooth brushing.

Following 20 days of pH cycling, the specimens were subjected to microdrill biopsy and surface microhardness analysis to determine fluoride uptake and remineralization ability, respectively.

**Results**

Clinpro™ Tooth Crème 0.21% w/w Sodium Fluoride Anti-Cavity Paste was significantly more effective than GC MI Paste Plus™ in this study on all measures tested.

- Clinpro Tooth Crème exhibited statistically significantly greater fluoride uptake into demineralized enamel than GC MI Paste Plus.
- Clinpro Tooth Crème exhibited statistically significantly greater remineralization than GC MI Paste Plus.

![Fluoride Uptake](image)

Fluoride Uptake [Mean +/- SEM]

Source: 3M ESPE internal data

![% Change in Surface Microhardness](image)

% Change in Surface Microhardness [Mean +/- SEM]

Source: 3M ESPE internal data
Extrinsic Stain Removal

The cleaning efficiency of fluoride-containing pastes is determined using the Pellicle Cleaning Ratio (PCR) test. This \textit{in vitro} test evaluates the ability of a fluoride-containing preparation to remove stained pellicle compared to that of a 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.\textsuperscript{14}

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 \textit{Sarcina lutea} for a period of four 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 and 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 Clinpro Tooth Crème while the others contained GC MI Paste Plus or a conventional 1100 ppm fluoride toothpaste. Following brushing, the color of each specimen was measured again. The change in color observed for each slurry was compared to that observed for a reference standard of calcium pyrophosphate to determine the PCR score.

Results

Clinpro Tooth Crème 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 Tooth Crème effectively cleans and whitens teeth.
**Abrasivity**

Fluoride-containing pastes need to strike a balance between effective cleaning and abrasivity. Pastes 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 tooth brushing.

**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). One slurry contained Clinpro™ Tooth Crème 0.21% w/w Sodium Fluoride Anti-Cavity Paste while another contained GC MI Paste Plus™ (900 ppm F⁻). 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) and 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 10 fold 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 Clinpro Tooth Crème was 59.58, well under the limit of 250. The REA value for Clinpro Tooth Crème was 3.95, well under the limit of 40.

Clinpro Tooth Crème provides gentle, effective cleaning of enamel and dentin.
DIRECTIONS FOR USE
Refer to packaging of Clinpro Tooth Crème for directions for use.

STORAGE
Refer to packaging of Clinpro Tooth Crème for storage information.

QUESTIONS AND ANSWERS
What advantages does Clinpro Tooth Crème offer over other professional fluoride preparations?
Clinpro Tooth Crème contains 950 ppm fluoride ion and an innovative tri-calcium phosphate ingredient. In laboratory studies, Clinpro Tooth Crème provided greater fluoride uptake and remineralization than GC MI Paste Plus, a 900 ppm fluoride preparation. In addition, Clinpro Tooth Crème has been shown in laboratory studies to reverse white spot lesions better than GC MI Paste Plus.

How long can my patients continue to use Clinpro Tooth Crème? Is there a time limit for treatment with Clinpro Tooth Crème?
With Clinpro Tooth Crème your patients can receive the benefit of 950 ppm fluoride in a gentle, fluoride-containing preparation that is less abrasive to enamel and dentin. Your patients can use Clinpro Tooth Crème in place of their conventional fluoride-containing preparation for the time necessary to control and prevent dental caries.
SUMMARY
Clinpro™ Tooth Crème 0.21% w/w Sodium Fluoride Anti-Cavity Paste:

- is used for the prevention of dental caries
- helps to prevent root caries
- contains 950 ppm fluoride ion
- contains an innovative tri-calcium phosphate ingredient
- cleans and whitens teeth
- exhibits greater fluoride uptake than GC MI Paste Plus™
- provides greater remineralization than GC MI Paste Plus
- helps reverse white spot lesions greater than GC MI Paste Plus

WARRANTY
3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE’s sole obligation shall be repair or replacement of the 3M ESPE product.

LIMITATION OF LIABILITY
Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.
REFERENCES


13. CDC MMWR Recommendations and Reports;August 17, 2001;50(RR14):1-42.
