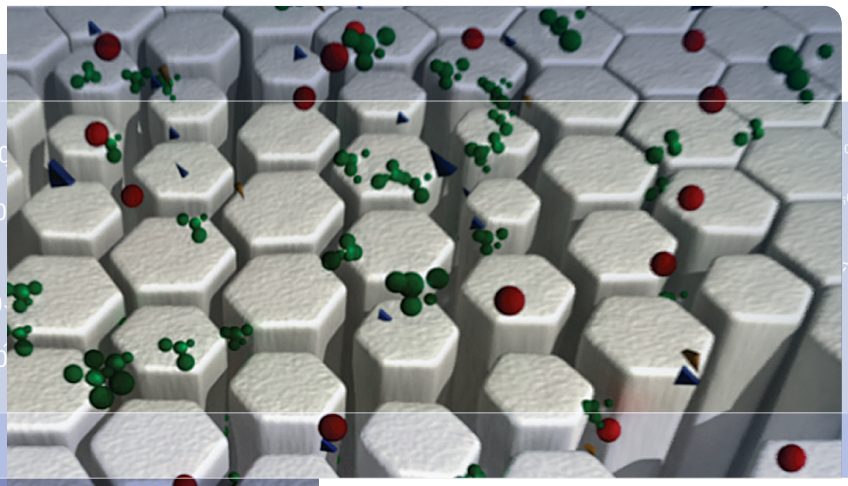
Tri-Calcium Phosphate (TCP)

A calcium technology exclusively from 3M ESPE



Fact Sheet

Innovative tri-calcium phosphate

- Close in composition to natural tooth mineral
- Defined and stable structure
- Predictable chemical properties
- Optimized to release calcium and phosphate at the tooth surface
- Protected calcium does not react with fluoride in toothpaste or varnish formulations during storage

Introduction

Although caries continues to be the most prevalent dental disease worldwide, significant reductions in dental caries have been reported over the past 30 years. The decline is attributed to nearly universal use of products containing fluoride, such as toothpastes and oral rinses, as well as professionally applied compounds containing higher concentrations of fluoride.

Fluoride is proven to prevent tooth decay. It does so by inhibiting demineralization, enhancing remineralization, and inhibiting bacterial activity in dental plaque. In recent years, we've advanced our understanding of the roles calcium and phosphate also play in remineralizing toothpastes and other dental products.

Clinical trials have shown that applying products with high concentrations of both calcium and fluoride may not result in greater protection against tooth decay.[1] That's because the *calcium and fluoride can combine during storage to form calcium fluoride—which renders the fluoride less effective* in preventing tooth decay.

However, 3M ESPE has introduced a proprietary calcium phosphate ingredient, Tri-Calcium Phosphate (TCP), that can be protected from unwanted interactions with fluoride during storage. This protected calcium additive works with fluoride to initiate high-quality mineral growth—acting as a catalyst to enhance remineralization and build a high-quality, acid-resistant mineral.[2] In addition, this innovative technology in toothpaste can be tailored to provide short- or long-term mineral delivery in a variety of dental products.

3M ESPE

A New Approach: Tri-Calcium Phosphate (TCP)

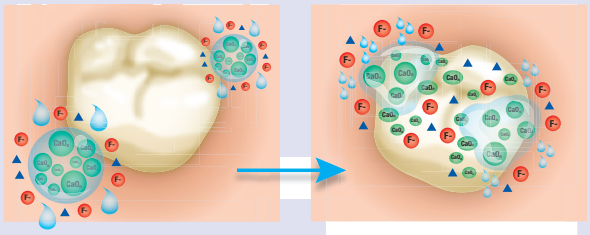
Functionalized tri-calcium phosphate, or TCP, is a "smart" calcium phosphate system that controls the delivery of calcium and phosphate ions to the teeth, works synergistically with fluoride to improve performance, but does not result in unwanted interactions with fluoride during product storage.

TCP is a partially soluble precursor to hydroxyapatite, the principle mineral of teeth, and is specially prepared so it can co-exist with fluoride in both aqueous or non-aqueous product formats.

Designed for a specific fluoride vehicle (e.g., dentifrice or varnish), TCP is milled with simple organic materials to create a functionalized TCP ingredient. This process ensures that prior to use, the active calcium sites are protected from premature interactions with fluoride, which could otherwise render both calcium and fluoride inactive.

Since the structure of TCP is similar to hydroxyapatite, once the functionalized calcium ions are released, they readily interact with the tooth surface and subsurface. While other calcium phosphate additives may require an acidic pH, which could limit the benefits to the tooth, functionalized TCP can offer optimal benefits when delivered in a neutral pH environment.

As functionalized TCP is less soluble relative to other forms of calcium phosphate[3], when applied as a dentifrice in formulation with fluoride, this TCP ingredient can enhance mineralization and help build a high-quality, acid-resistant mineral—without the need for high levels of calcium.



Organic components (often surfactants) have an affinity for tooth surfaces—and can carry calcium to the tooth surface, protected from fluoride ions. Saliva activates the protected calcium compound by degrading the protective coating and releasing the calcium, making it available to the tooth surface along with the fluoride.

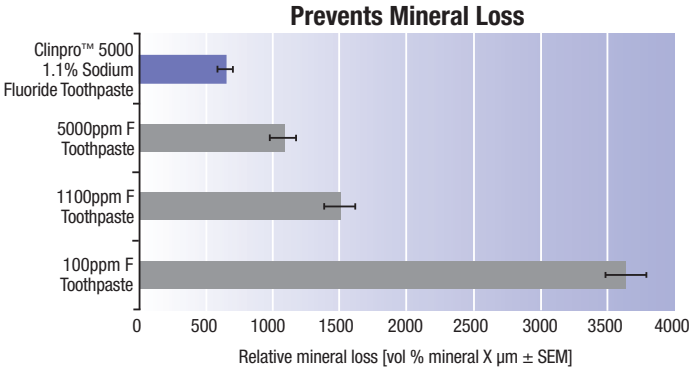
Clinical Applications Fluoride Toothpaste

As the functionalized TCP ingredient is protected from unwanted interactions with fluoride within the toothpaste during storage, it remains stable and allows for more fluoride availability. During brushing, both fluoride and the TCP ingredient are delivered to the tooth and provide enhanced remineralization and added protection against demineralization. Several laboratory studies have proven superior performance when the TCP material is added to fluoride toothpastes at optimal concentration.

Protects against lesion initiation and progression[4]

The purpose of this study was to determine how well different toothpaste formulations protect against carious lesion formation and progression.

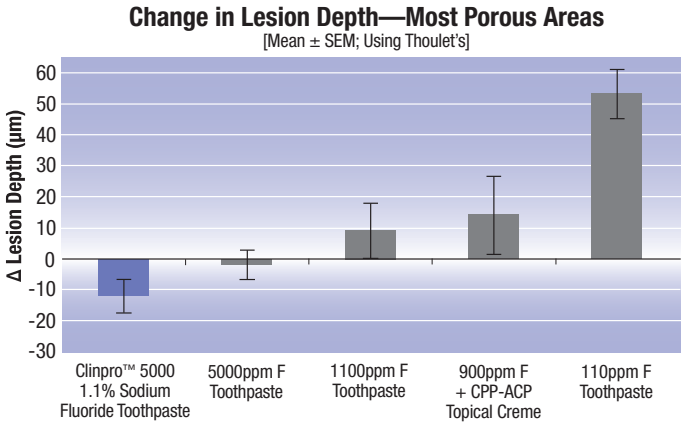
In this study, a well-established pH-cycling model was used to mimic enamel lesion initiation and progression. Sound tooth enamel samples were subjected to periods of demineralization with an acid solution, and remineralization with various toothpaste treatments and artificial saliva. Samples were analyzed using cross-sectional microhardness to ensure the entire lesion body was analyzed.



Conclusion: While both 5000 ppm fluoride toothpastes inhibited lesion progression greater than the OTC-level toothpaste, 3M™ ESPE™ Clinpro™ 5000 1.1% Sodium Fluoride Anti-Cavity Toothpaste with TCP provided superior protection against lesion initiation and progression.

Reduces lesion depth[5]

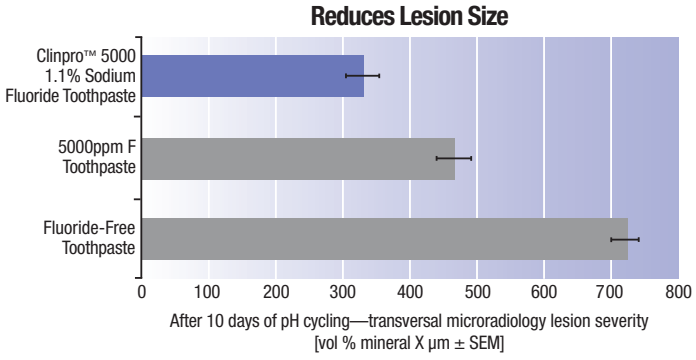
The purpose of this study was to evaluate the de/remineralization effect on enamel lesions after treatment with products containing fluoride, using a pH-cycling model in vitro. Human enamel samples were demineralized to create enamel lesions and then divided into treatment groups. The daily pH-cycling period consisted of a 2-minute treatment twice a day with product, followed by periods of demineralization and artificial saliva over a 14-day period. Samples were evaluated using Polarized Light Microscopy analysis.



Conclusion: Clinpro 5000 toothpaste reduced the average lesion depth by more than 10%, demonstrating remineralization was occurring deep in the lesion with the most severe damage.

Repairs early lesions[6]

The purpose of this study was to evaluate how well different toothpaste formulations enhance remineralization of existing white spots. In the study design, white spot lesions on bovine enamel samples were subjected to periods of demineralization, remineralization and toothpaste treatments. After cycling the lesions for 10 days, lesions were evaluated.



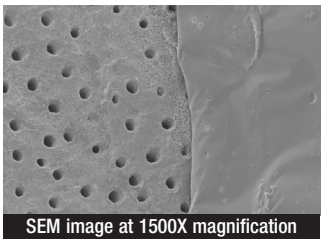
Conclusion: Results indicate that Clinpro 5000 toothpaste provides superior remineralization at both the enamel surface and deep within the lesion.

Clinical Applications Fluoride Varnish

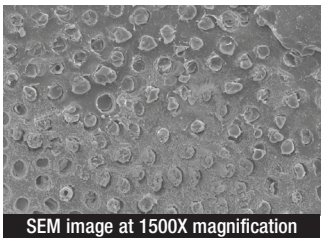
Decreases hypersensitivity

Tri-calcium phosphate, when added to Vanish™ 5% Sodium White Varnish, can help decrease hypersensitivity by depositing high-quality, acid-resistant mineral that occludes exposed dentinal tubules.

Vanish white varnish coats, penetrates and blocks tubules.



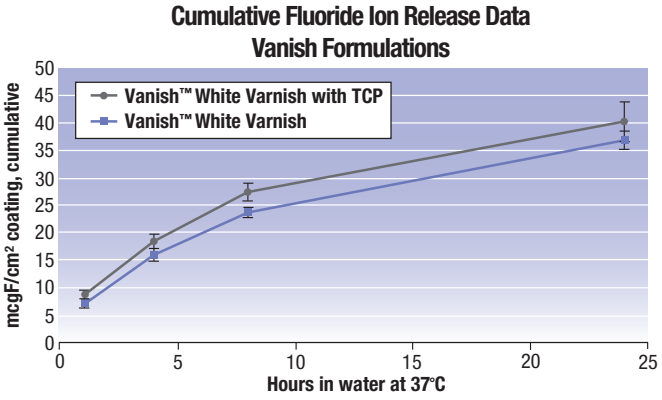
Vanish™ 5% Sodium Fluoride White Varnish covers and occludes open tubules for immediate relief.
Source: 3M ESPE internal data



After the bulk of the varnish has been removed from the surface, Vanish™ 5% Sodium Fluoride White Varnish continues to block tubule openings.
Source: 3M ESPE internal data

Sustains fluoride availability[7,8]

In a laboratory study done with fluoride varnishes, Vanish white varnish was tested before and after addition of functionalized TCP.



Conclusion: Results showed that addition of this novel TCP ingredient to Vanish white varnish does not inhibit fluoride availability.

Results of a related clinical study done with Vanish white varnish showed no significant differences in mean fluoride salivary levels before and after addition of functionalized TCP for at least 4 hours after application.

Preventive products with calcium-based technologies exclusively from 3M ESPE

3M ESPE's exclusive TCP ingredient is the latest advancement in preventive care. This breakthrough technology has been added to our anti-cavity toothpaste and fluoride varnish treatment, raising effectiveness in enhancing remineralization, preventing demineralization of tooth structure, or decreasing tooth hypersensitivity.

Clinpro™ 5000
1.1% Sodium Fluoride Anti-Cavity Toothpaste

- Prevents demineralization and enhances remineralization of tooth structure

Vanish™
5% Sodium Fluoride White Varnish with TCP

- Decreases tooth hypersensitivity

Summary

For the clinician prescribing a treatment plan to prevent tooth decay or tooth hypersensitivity, products with 3M ESPE's exclusive TCP ingredient would be highly recommended. Results of third-party comparative studies **suggest the *f*TCP ingredient may provide added protection above fluoride alone.** TCP is a proprietary ingredient in both Clinpro 5000 Anti-Cavity Toothpaste and Vanish 5% Sodium Fluoride White Varnish with TCP.

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4. JDB Featherstone, M Rapozo-Hilo, C Le, *Inhibition of Demineralization and Promotion of Remineralization by 5000 ppm F Dentifrices*, Journal of Dental Research, 2010, Special Issue B, Abs 386, Vol. 89.
5. MM Hogan, JD Harless, JS Wefel, *Lesion Progression After Use of Fluoride and CaP Containing Dentifrices*, Journal of Dental Research, 2010, Special Issue B, Abs 3230, Vol. 89.
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8. V Kolb, P Klaiber, A Pfarrer, R Farlee, *In Vivo Study: Migration and Salivary Fluoride After Varnish Application*, AADR 2010, Abstract #312.

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