

# Other Topics

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# A Novel Dentifrice Technology for Advanced Oral Health Protection: A Review of Technical and Clinical Data on Stabilized Stannous Fluoride and Sodium Hexametaphosphate Dentifrice

**Crest**  
**PRO-SANTÉ**

Full text available in the Research Database at [www.dentalcare.com](http://www.dentalcare.com)

Reference: Baig A, He T. *Compend Contin Educ Dent.* 2005;26(Suppl 1):4-11.

## CONCLUSION

- This is a review of clinical and laboratory data for Crest® Pro-Health™ to support claims of multiple benefits: antibacterial, antiplaque, antigingivitis, antihypersensitivity, anticaries, anticalculus, and whitening.

## REVIEW

- Globally, dentifrice plays an important role in good oral hygiene. Toothpastes aid in general cleaning and also serve as an excellent vehicle for delivery of agents that deliver therapeutic and cosmetic benefits.
- Key examples of using dentifrice to provide added benefits include the introduction of the first fluoridated toothpaste clinically proven to fight caries in 1955 (Crest® Cavity Protection) and the launch of the first tartar control dentifrice (Crest® Tartar Control) in the mid-1980's.



- Numerous agents have been evaluated during the last three decades. The multi-benefit segment has been a focus area, which is very popular among U.S. consumers.



**Crest**<sup>MD</sup>

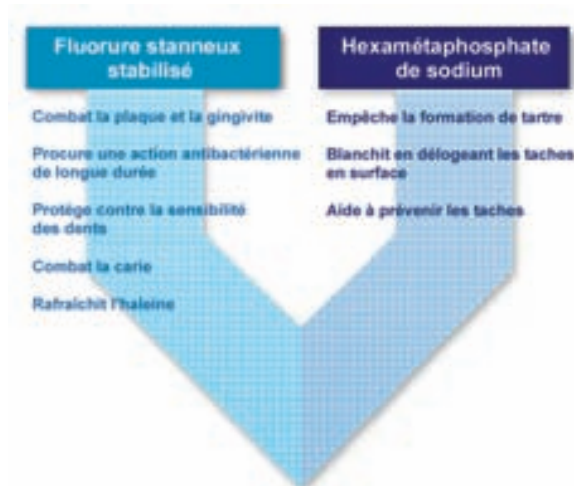
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# A Novel Dentifrice Technology for Advanced Oral Health Protection: A Review of Technical and Clinical Data on Stabilized Stannous Fluoride and Sodium Hexametaphosphate Dentifrice

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## REVIEW (continued)

- Delivering multiple benefits from one dentifrice may involve combining a drug agent and non-drug agents for therapeutic and cosmetic benefits (e.g., anticavity toothpaste with tartar protection) or incorporating two different active agents for more than one therapeutic indication (e.g., anticavity plus antihypersensitivity toothpaste).
- In either case, providing therapeutic and/or aesthetic benefits through a combination of separate ingredients into a single formulation can be limited by product stability, technical performance, ingredient safety, aesthetics, cost and regulatory considerations. Strategically, employing drug agents that provide multiple therapeutic benefits helps overcome many of these technical limitations.
- Recent advances have enabled development of a toothpaste formulation (Crest Pro-Health) that combines stabilized stannous fluoride and sodium hexametaphosphate. This formula meets the evolving health and cosmetic needs of patients. This paper reviews the data supporting this novel technology



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# Practice-Based Evaluation of a Stannous Fluoride-Sodium Hexametaphosphate Dentifrice: Crest® Pro-Health™



## KEY RESULTS/CONCLUSIONS

- Crest Pro-Health showed excellent patient and professional acceptance as well as noticeable oral health improvements. These factors are important in driving compliance.
- In this practice-based study, nearly 7 of 10 dental professionals observed improvements in their patients' oral health and two-thirds of patients intended to continue using Crest Pro-Health following the extended use evaluation.

## OBJECTIVE

To evaluate the professional observations of dentists/hygienists and the personal experience of patients based on their use of Crest Pro-Health toothpaste over an extended period.

## MATERIALS AND METHODS

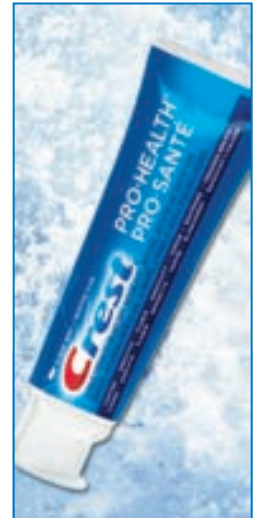
- Dentists/hygienists across the US were invited to participate in the study. Enough Crest Pro-Health samples were provided to supply a small group of patients for 3-4 months.
- Dental professionals assessed their patients' oral health status at the beginning of the evaluation and at their return visit. Conditions included gingival bleeding, inflammation, calculus, extrinsic stain and sensitivity.
- Patients completed a questionnaire at their return visit.

## RESULTS

- 1267 surveys were collected from dentists/hygienists and 1078 from patients.
- Approximately 75% of evaluations were based on 3-4 months of use. The remaining patients used the product up to 6 months.
- Specific responses analyzed were those where,
  - (i) dentists/hygienists provided pre- and post-oral health assessments and gave answers to questions, and
  - (ii) patients rated the product overall and gave answers to questions.

### Professional Responses

- Two-thirds of all professionals observed improvement in their patients' oral condition after the trial period. Specific improvements include:
  - gingival bleeding
  - gingival inflammation
  - calculus formation
- Improvement was also noted by 61% of professionals for sensitivity and 57% of professionals for staining.
- 91% of professionals who observed improvement would recommend Crest Pro-Health.
- Overall, 8 in 10 professionals said they would recommend Crest Pro-Health.



# Practice-Based Evaluation of a Stannous Fluoride-Sodium Hexametaphosphate Dentifrice: Crest® Pro-Health™



## RESULTS (continued)

### Patient Opinion

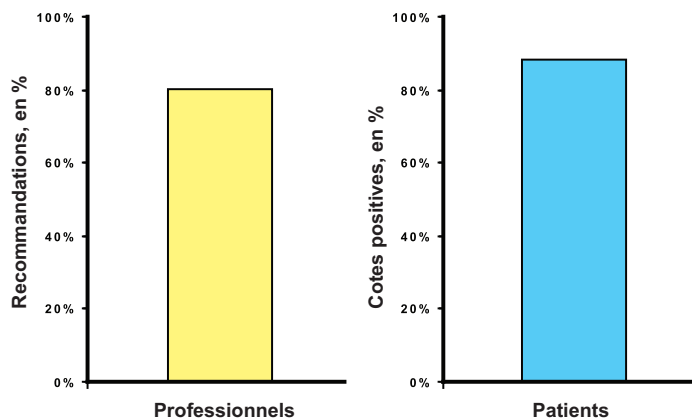
- 88% of patients rated Crest Pro-Health positively (Excellent/Very Good/Good).
- 77% of trial participants who had noticeable improvements in their oral health intended to continue using Crest Pro-Health. Two-thirds of all patients in the evaluation intended to continue using Crest Pro-Health.
- Roughly 9 of 10 patients rated Crest Pro-Health positively for “keeping mouth healthy”, “cleaning teeth thoroughly”, being a “comprehensive toothpaste”, making “gums healthier” and “freshening breath”.
- 8 of 10 subjects rated Crest Pro-Health positively for reducing surface stains and gingival bleeding.

## CLINICAL COMMENT

Crest Pro-Health is a unique dentifrice formulation combining stannous fluoride and sodium hexametaphosphate. Stannous fluoride is an antibacterial fluoride that helps protect against plaque, gingivitis, caries and dentinal hypersensitivity. Sodium hexametaphosphate is an advanced whitening and anticalculus agent. In rigorous clinical trials, the stannous fluoride-sodium hexametaphosphate dentifrice technology has demonstrated statistically significant improvements for a broad range of conditions, such as gingival bleeding, gingival inflammation, tooth sensitivity, extrinsic stain formation, and supragingival calculus. Findings from this large, practice-based assessment complement the clinical results. In combination, the clinical data and practice-based evaluations provide sound evidence for incorporating Crest Pro-Health in patients’ daily oral hygiene regimen.



## Percentages of professionals indicating they would recommended Crest Pro-Health and percentage of patients who rated Crest Pro-Health positively (good/very good/excellent)



# Retention of Tin in Dental Plaque: Pharmacokinetic Modeling



**Reference:** Scott D, Coggan J, Cruze C, Johnson R, Baker R, He T. *J Dent Res.* 2007;86 (Spec Iss): Abstract 1874.

## CONCLUSION

- Tin is cleared from saliva rapidly but very well retained in dental plaque. The prolonged retention of tin in dental plaque offers the basis for its anti-plaque and anti-gingivitis benefits

## OBJECTIVE

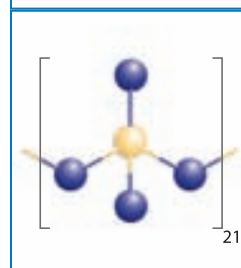
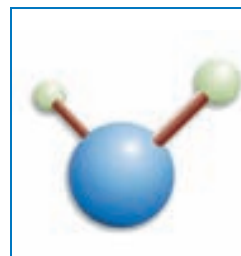
Stannous ion is a divalent metal cation with antimicrobial properties. It has been used in the oral cavity, most commonly delivered in the form of a dentifrice, for treatment and prevention of plaque and gingivitis. The objective of this research is to evaluate the time-course fate of total tin in saliva and dental plaque

## MATERIALS AND METHODS

- 20 generally healthy subjects were enrolled in the study.
- Baseline saliva and plaque samples were taken after one week of acclimation using a sodium fluoride dentifrice. Subjects then rinsed with an experimental 0.454% stannous fluoride/sodium hexametaphosphate dentifrice slurry for 60 seconds.
- Saliva samples were collected at 5, 15, 30, 45, 60, 90 minutes, 2, 3, 4.5, and 6 hours post rinsing. Supergingival plaque samples were collected using a sterile plastic curette at 15, 30, 60 minutes, 2, 3, 4.5, and 6 hours post rinsing.
- Sample times and quadrants were evenly distributed across the subjects to ensure proper statistical representation of these parameters. Samples were assayed for total tin content and simultaneously modeled using an unusual two compartment model.

## RESULTS

- The concentration of tin in saliva dropped rapidly immediately after dentifrice slurry administration. The plaque tin profile indicated that the oral surfaces were readily charged with tin during administration. There was a small additional accumulation after administration.
- The plaque tin levels changed very little over the course of 6 hours. Modeling indicates that there is an obvious kinetic relationship between saliva and plaque compartments and that tin is very well retained in and slowly released from plaque into saliva. Additionally, both compartments were simultaneously loaded during administration.





# Progress Regarding the Use of Stannous Fluoride in Clinical Dentistry



Reference: Tinanoff N. *J Clin Dent.* 1995;6:37-40.

## CONCLUSION

- Methods have been developed to stabilize stannous fluoride ( $\text{SnF}_2$ ) in dentifrice formulations. Clinical trials have shown that stabilized  $\text{SnF}_2$  markedly reduces gingivitis and has antibacterial effects that are additional to those of fluoride.

## OBJECTIVE

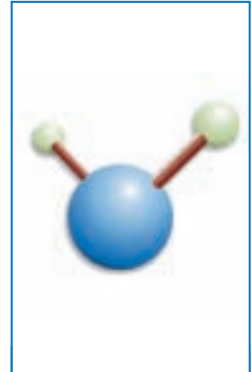
To examine the methods of stabilizing  $\text{SnF}_2$ , present evidence of its antibacterial properties, review the proposed mechanisms for these effects, and discuss the clinical factors important for maximizing the antimicrobial properties of  $\text{SnF}_2$ .

## KEY MESSAGES

- **Stability and biological activity of  $\text{SnF}_2$ :** manufacturers have developed techniques to stabilize  $\text{SnF}_2$  for prolonged time periods in aqueous dentifrice formulations. Chelating agents are used that bind stannous fluoride; stannous reservoirs act as a stannous ion supply and as an antioxidant.
- **Antiplaque and antigingivitis properties of  $\text{SnF}_2$ :** most studies have found that stabilized  $\text{SnF}_2$  has anti-plaque effects; marked effects on gingivitis have been reported. Most often,  $\text{SnF}_2$  has been used twice daily at concentrations between 0.1 and 0.45%
- **Anticaries effects:**  $\text{SnF}_2$  has been reported to reduce the bacterial groups that cause dental caries, but mainly when used twice daily at a concentration of 0.4%.
- **Mechanism of action:** Fluoride compounds are known to foster remineralization of partially demineralized enamel.



- In addition,  $\text{SnF}_2$  has antibacterial and physicochemical effects, such as the covering of exposed dentinal tubules to reduce dentinal hypersensitivity.





# Recent Advances in Clinical Research on Toothpastes and Mouthwashes: Clinical Efficacy of Commercial Products for Gingivitis, Tartar Control and Antimicrobial Activity



Reference: White DJ. *J Clin Dent.* 1997;8:37-8.

## CONCLUSION

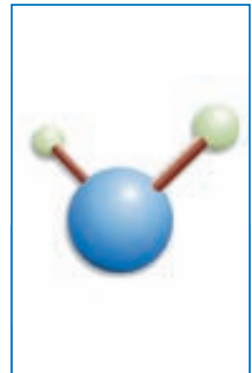
- This special issue summarizes comparative research on therapeutic oral care products – including stabilized stannous fluoride dentifrice – to help guide professionals in making recommendations for home care products.

## OBJECTIVE

This paper introduces a special issue of clinical research comparing various oral care products for therapeutic efficacy. It also discusses the complex aspects of developing formulations with biologically active ingredients for controlling dental diseases.

## MATERIALS AND METHODS

- Commercial dental products, such as toothpastes and mouthwashes, promote improved dental hygiene.
- Chemotherapeutic additives, such as fluorides, have led to the reduction and control of dental caries, hypersensitivity, supragingival calculus, plaque and gingivitis in Western countries.
- Consumers are faced with a multiplicity of choices and may need professional help in choosing the right product for their oral health needs.
- Professionals in turn may rely on experience of a product, professional endorsements, and/or research data; the latter is the hardest to interpret.

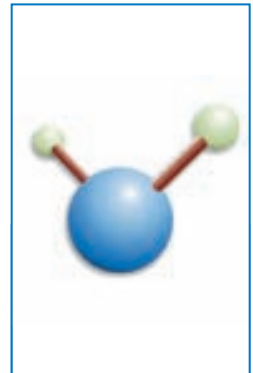


# Recent Advances in Clinical Research on Toothpastes and Mouthwashes: Clinical Efficacy of Commercial Products for Gingivitis, Tartar Control and Antimicrobial Activity



## MATERIALS AND METHODS (continued)

- Valid research data should show, at a minimum, efficacy for a product against a placebo, and where possible comparisons to other commercially available products
- Highlights from the papers included in this issue, which include direct comparisons between commercial dentifrices and/or mouthwashes include:
  - the prevention and treatment of gingivitis and gingival bleeding with a stabilized stannous fluoride dentifrice compared to a triclosan-copolymer dentifrice;
  - the control of gingivitis with a stabilized stannous fluoride dentifrice compared to an essential oils mouthrinse and a baking soda and peroxide dentifrice;
  - the antimicrobial actions of a stabilized stannous fluoride dentifrice compared to a baking soda and peroxide dentifrice and an essential oil mouthrinse.



# A "Return" to Stannous Fluoride Dentifrices



Reference: White DJ. A "return" to stannous fluoride dentifrices. *J Clin Dent.* 1995;6:29-36

## CONCLUSION

- *In vivo* and *in vitro* data suggest that a stabilized stannous fluoride dentifrice may be of significant benefit for oral health, showing superior efficacy against caries as compared to the original stannous fluoride dentifrice introduced in the 1950s.

## OBJECTIVE

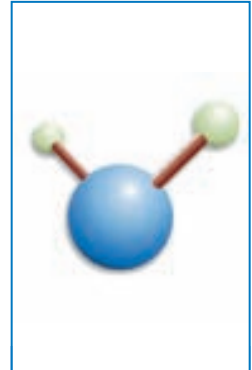
To examine the rationale for a "return" to the use of stannous fluoride in toothpastes, and to introduce the research papers showing the safety and efficacy of a stabilized stannous fluoride dentifrice.

## KEY MESSAGES

- Stannous fluoride dentifrices were introduced in the 1950s.



- Research underpinned their use at the time and limitations led to other fluoride sources being sought in the 1960s and 70s.
- Original stannous fluoride ( $\text{SnF}_2$ ) dentifrices had limited stability and formulation flexibility, which led to the development and commercialization of sodium monofluorophosphate and sodium fluoride dentifrices for caries control. However, unlike  $\text{SnF}_2$  these two fluoride agents do not protect against plaque, gingivitis or dentinal hypersensitivity.
- Changing patterns of oral disease have focused research on agents that provide benefits for dental caries and gingivitis, and the potential benefits of  $\text{SnF}_2$  have been reassessed.
- The formulation stability of original  $\text{SnF}_2$  toothpastes was improved to give sufficient levels of bioavailability for both anticaries and antigingivitis activity.



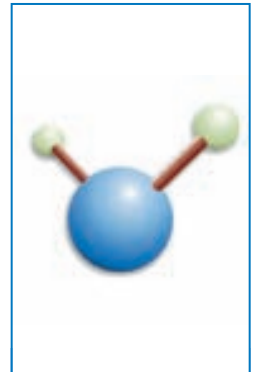
# A "Return" to Stannous Fluoride Dentifrices



## KEY MESSAGES (continued)



- Clinical studies have demonstrated that stabilized SnF<sub>2</sub> dentifrice is effective in reducing gingivitis and gingival bleeding. Antimicrobial activity interfering with plaque metabolic processes associated with plaque virulence appears to be the mechanism for preventing gingivitis.
- A battery of tests predictive of clinical performance show stabilized SnF<sub>2</sub> dentifrice provides improved anticaries reactivity compared to original stannous fluoride dentifrices.
- Together, laboratory and clinical data supports the 'return' to SnF<sub>2</sub> dentifrice in stabilized formulations.



# Comparative Intraoral Tolerance of Sodium Hexametaphosphate and Pyrophosphate Antitartar Dentifrices



Reference: Gerlach RW. J Clin Dent. 2002;13:29-32.

## CONCLUSION

- In this study, the 7.0% sodium hexametaphosphate dentifrice was exceedingly well-tolerated, with significantly fewer symptoms and superior overall tolerance compared to the marketed antitartar dentifrice control.

## OBJECTIVE

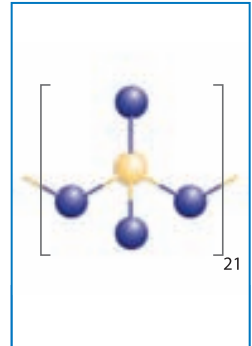
To assess the relative acute oral tolerance of a dual phase, tartar control dentifrice containing 7.0% sodium hexametaphosphate.

## MATERIALS AND METHODS

- A randomized, controlled 4-day clinical trial.
- 159 healthy adult volunteers were randomly assigned to the experimental sodium hexametaphosphate dentifrice or a marketed, single phase, antitartar dentifrice control containing 5.0% ionic pyrophosphate.
- A detailed oral soft tissue examination and interview were conducted each day by blinded evaluators to elicit clinical signs and symptoms associated with *ad lib* use of the assigned dentifrice.

## RESULTS

- A total of 24 subjects (15% of the study population) had new symptoms/signs after baseline.
- By treatment, 9% of subjects in the sodium hexametaphosphate group had new findings, compared to 21% of subjects in the pyrophosphate group, and these groups differed statistically ( $p < 0.03$ , two-sided) with respect to occurrence.
- In addition, onset, severity, duration and clinical presentation were generally milder in the sodium hexametaphosphate group compared to the pyrophosphate control. Only one subject (in the pyrophosphate group) discontinued treatment early due to oral intolerance.



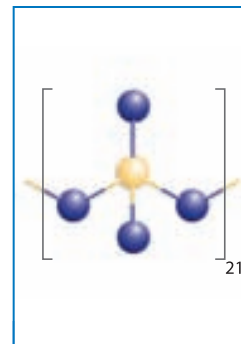
# Comparative Intraoral Tolerance of Sodium Hexametaphosphate and Pyrophosphate Antitartar Dentifrices



## RESULTS (continued)

### Comparison of Subject-Related and/or Examiner-Observed Findings by Treatment, All Evaluable Subjects (N=158)

	Sodium hexametaphosphate N (%)	Pyrophosphate N (%)	p-value
Signs or Symptoms	7 (8.7)	17 (21.8)	0.027
Both Signs and Symptoms	1 (1.3)	7 (9.0)	0.033
Signs	6 (7.5)	10 (12.8)	0.302
Symptoms	2 (2.5)	14 (18.0)	0.013



# Morphology of in Vivo Salivary Pellicles after Exposure to Dentifrices



Reference: van der Mei HC, White D, Dijkman AH, De Vries J, Busscher HJ. J Dent Res 2004;83. Abstract 4029.

## CONCLUSION

- The roughness and thickness of salivary pellicles is influenced by routine hygiene and oral products including hexametaphosphate containing dentifrices. Mouth perception anecdotally appears also to be influenced by pellicle thickness and structure.

## OBJECTIVE

Salivary pellicles are frequently exposed to dentifrices with an impact on their thickness and surface roughness. One can speculate that both properties of salivary pellicles are likely important for oral biological properties as well as intraoral perception of cleanliness.

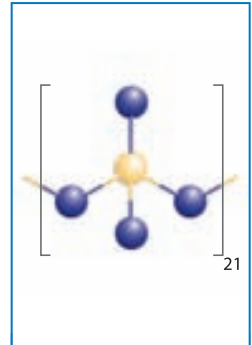
The aim of this study is to compare the pellicle composition and morphology after exposure to a dentifrice containing fluoride and sodium lauryl sulphate (Crest® Regular, CR) and a dentifrice supplemented with hexametaphosphate (Crest® Dual Action Whitening, CDAW).

## MATERIALS AND METHODS

- Enamel blocks were fixed in the flanges of dentures and worn by two denture wearers up to 3 days. Daily oral hygiene on one side of the mouth was established by flushing with a dentifrice slurry, while the other side was brushed. Immediately after the experimental period, samples were removed and analysed by XPS (X-ray photoelectron spectroscopy) for pellicle thickness and AFM (Atomic force microscopy) for surface roughness.
- In separate studies, mouth feel was evaluated on a scale from -2 (bad) to 2(good) in ten volunteers with a full dentition at various times during the day after one weeks use of dentifrices.

## RESULTS

- On average, the use of CDAW yielded smooth pellicle surfaces with a roughness of around 35 nm, which was three times smoother than after use of CR.
- Moreover, in vivo pellicles, after preparation for XPS, had a thickness of 4.0 nm after CR, while after use of CDAW the thickness had decreased to 3.2 nm. These changes were concurrent with a strongly superior mouth feel after the use of CDAW (38.9 % above neutral throughout day) as compared with volunteers using CR (19.9 %).











For more information about advanced dentifrice  
technologies from Crest, visit:  
**[dentalcare.com](http://dentalcare.com)**

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