

Choosing a Toothpaste: What's the Big Deal?



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Conflict of Interest Disclosure Statement

- Ms. Campbell has done consulting work for Procter & Gamble. She has no relevant financial relationships to disclose.

Introduction – Toothpaste

This course will establish why all fluoride toothpastes are NOT the same and assist the learner in understanding what differentiates them and makes a particular toothpaste the best fit for an individual patient. The important role of mechanical plaque removal by toothbrushing in light of the prevalence of common global oral issues is outlined, together with the current understanding of toothbrushing efficiency and the opportunities for adjunct chemical intervention through dentifrice. Differences in toothpaste fluorides, anti-gingivitis chemotherapeutic agents, cosmetic ingredients, safety considerations such as abrasivity, and other indication-targeting agents (e.g., desensitizing) are reviewed to highlight the need to compare toothpastes' marketed indications and any associated product research to assist patients and clinicians in customized, informed product selection.

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Overview

Toothbrushing with a dentifrice is the most widely practiced means of oral hygiene and foundational to home care practice. Toothpaste is a cost-effective vehicle for the incorporation of therapeutic agents: historically fluoride for caries prevention, and more recently cosmetic whitening ingredients, as well as chemotherapeutic active agents that target gingivitis emanating from the lack of complete plaque removal common to the average brusher. Despite the widespread perception

that toothpastes are relatively interchangeable, their benefits and clinical effectiveness vary, being highly dependent upon active agent efficacy and the precise formulation and compatibility of all ingredients. Deciding between the plethora of marketed toothpastes with competing claims can be confusing to consumers, and even to clinicians who find it challenging to keep up with new product introductions and clinical research.

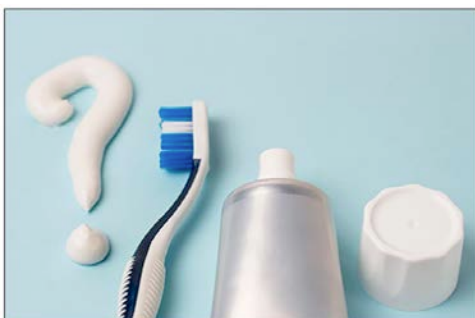
Learning Objectives

Upon completion of this course, the dental professional should be able to:

- Discuss the importance of toothbrushing, based on current oral disease prevalence, and the criticality of plaque removal in disease prevention.
- Explain the basis for the incorporation of agents in toothpaste formulation for disease prevention and treatment.
- Review the differences between the common fluorides found in commercial toothpastes.
- Describe the method of action and benefits of stannous fluoride as an antimicrobial chemotherapeutic agent in dentifrice.
- Identify other common toothpaste agents that address patient indications, both therapeutic and cosmetic.
- Describe how abrasivity is related to toothpaste safety.
- Recognize the importance of laboratory and clinical research in establishing and supporting toothpaste claims.
- Apply the understanding about toothpastes' relative benefits to assist patients in selecting the best dentifrice to meet their unique oral health needs.

Introduction

There is a large and growing selection of toothpastes on display for patients when they shop for oral health products, and they likely have asked you to help guide them. In reality, is toothpaste even necessary? Is it a meaningful contributor to dental health? If so, are there truly any substantive differences between dentifrices? To answer these questions, this course will dive into the unique formulation elements and various benefits provided by each category of marketed toothpastes.



You'll learn whether or not, "all toothpastes are basically the same," and how to evaluate products so you can confidently recommend the best fit for a patient's unique needs.

Consider you're standing in a huge car lot. Overwhelmed with decision paralysis by the myriad options, you give up and simply buy the cheapest vehicle, or the car with the most eye-catching color, or the one you've seen a neighbor driving. Because after all, a car is a car, right?

While this is a silly, implausible scenario, the truth is, a similar mindset in purchase decision-making for less expensive items can set in when the choices are many. The consumer is unaware of the merits (or lack thereof) of the options under consideration. In the realm of personal health products, choosing from a vast array of marketed toothpastes may seem insignificant and 'low stakes' to the uninformed/typical buyer, leading to selections based solely on price point or the lure of flashy packaging or creative shopping aisle display.

Oral Hygiene: Why?

Esthetics/Cosmetics

While hygiene standards have improved over time, the motivations for cleaning one's teeth and mouth were presumably the same for the ancients as for 21st century adults: a desire for fresher breath, smoother-feeling teeth, a healthier mouth, and shinier, less yellow teeth. The Romans, for example, reportedly coveted white teeth and used eyebrow-raising substances like human urine in an attempt to brighten them.¹ In more modern times, slogans such as *"You'll wonder where the yellow went, when you brush your teeth with Pepsodent"* (1930s)



Source: [Look Magazine; April 16, 1946.](#)

captured the imagination of Americans and highlighted the growing availability of cosmetic self-care products for a more engaging smile.²

Now in the current era of ubiquitous social media and selfie culture, an appealing smile is nearly universally the goal. Rightly or not, a white smile is often perceived to be synonymous with a healthy smile and conveys youth and vitality. In a survey by the American Academy of Cosmetic Dentistry, nearly 100% of adults reported the smile is a key social asset, 96% said an attractive smile boosted one's appeal with the opposite sex, and "whiter and brighter teeth" was the top response when asked what they'd like to improve about their smile.³ Not surprisingly, the demand for cosmetic dental procedures has grown exponentially.⁴ Professional or self-administered tooth whitening and whitening toothpastes are extremely popular.⁵ One thing, however, has never changed: the fact that a bright, healthy smile starts with basic, economical oral hygiene: the daily clearing/removal by the patient of odor-causing food debris, dental plaque, and superficial, dulling stains for enhanced esthetics and a fresher mouth and breath.

Gingival/Periodontal Health

Another key reason for performing oral hygiene is to maintain adequate gingival and periodontal health. While more informed patients may be aware of and motivated by the implications of not practicing thorough plaque removal, global epidemiological statistics show most individuals fall short in adequate plaque control for disease prevention. The FDI World Federation cites periodontal disease (and its precursor plaque-induced gingivitis) as one of the two most common (the other being dental caries, covered later in this course), and largely preventable – oral health conditions around the world.⁶

With this in mind, daily thorough oral hygiene is essential, given that the amount of dental plaque grows when not removed and its composition becomes increasingly more virulent, creating a state of dysbiosis which in turn triggers inflammation. Historically, efforts to prevent esthetically displeasing smiles and the initiation of gingivitis have thus largely centered around plaque control using the mainstay of the daily personal oral hygiene regimen – the toothbrush.

The Indispensable Toothbrush

The first US patent on a toothbrush was awarded in 1857,⁷ (Figure 1) but humans have been attempting to clean their teeth since at least 3500 B.C., when “chew sticks” were fashioned from twigs in Mesopotamia. The prototype for our modern toothbrushes probably originated in China in 1498 in the

form of a bone or bamboo-handled brush with hog bristles, but it would be another 400 years before the first nylon-bristled brushes were introduced.⁸

Prior to mass-produced affordable toothbrushes, men and women in the past seeking better breath and cleaner teeth had to get creative with dental plaque and food debris removal implements (e.g., sponges, metal toothpicks, stiff quills,)^{9,10} Today's better access to easy-to-use cleaning tools means toothbrushing is now normative in developed regions globally. The 2003 Lemelson-MIT Invention Index survey of Americans revealed that the toothbrush beat out even cars and phones as the top invention they couldn't live without.¹¹ A rapid evolution in toothbrush design for cleaning effectiveness and safety over the last several decades has brought a wide, diverse selection of manual and electric toothbrushes that offer basic or more advanced handle and bristle configurations and functionality.

The utility of a toothbrush for better dental and gum health and a more cosmetically appealing smile is predicated on mechanical debridement: the sweeping action that can lift and remove discoloring and odor-causing debris, as well as disease-inducing bacteria imbedded within dental plaque biofilms and on the tongue. Beginning with Van Leeuwenhoek's 1680 discovery of microbes in plaque,¹² ongoing scientific inquiry has illuminated the dynamics of the oral microbial flora and shed light on

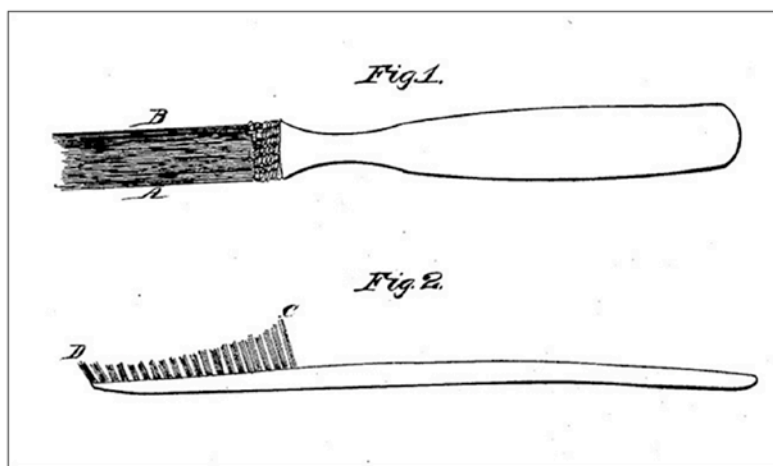


Figure 1. Wadworth's Patent for the First United States Toothbrush.⁷

the contributions of undisturbed, pathogenic plaque in the etiology of the most common and pressing oral public health concerns. The toothbrush – from its crude beginnings centuries ago to the advanced models available today – remains a primary weapon in the fight against gingivitis/periodontitis, and against tooth decay when it acts as a delivery vehicle for anti-caries agents (see Toothpaste as a Vehicle).

Toothbrush + Toothpaste = Synergy

When performed well, toothbrushing can significantly reduce dental plaque in a single brushing session.¹³ If this occurs chiefly via mechanical means, is toothpaste superfluous? Several investigations have found that combining dentifrice with toothbrushing did not provide meaningfully greater plaque removal versus “dry brushing” (i.e., without toothpaste) when measured immediately after brushing.¹⁴ Should brushing without dentifrice then be the standard?

Before considering the merits of dentifrice exclusive of plaque volume reduction, it should be noted that the concept of toothbrushing without toothpaste has not typically proven popular. Dudding and colleagues found that about one-half of participants in a study who were assigned to brushing without paste (water only) dropped out of the trial.¹⁵ Van der Sluijs et al. reported that subjects in two investigations who were assigned to brush without dentifrice rated their experience negatively (means of 3.21 and 3.01 on a perception scale of 0-10).¹⁶ Combining dentifrice with a toothbrush is the norm, and produces the widely sought freshness, flavor, and mouth refreshment that cannot be achieved with water brushing alone, and likely motivates regular usage.¹⁵⁻¹⁷ Data



from the Simmons National Consumer Survey and census data showed the vast majority of Americans (306.19 million; 94%) use toothpaste,¹⁸ thus it seems reasonable to conclude that even if a professional recommendation called for skipping toothpaste when brushing, most would probably not heed it.

What Exactly is Dentifrice?

Modern dentifrices have their early origins in various attempts over the centuries at creating creams or powders to remove tooth debris and combat foul breath. In *The History of Toothpaste*,¹⁹ author Frank Lippert recounts how ancient Egyptian history records a dental cream concoction of egg shells, pumice, myrrh, and powdered oxen hooves. The Romans may have been the first to incorporate malodor-concealing flavoring in the form of bark and charcoal, but overall, primitive toothpastes were poor tasting and overly abrasive. By the 18th century, tooth powders were more common, but they too were highly abrasive due to ingredients such as crushed earthenware. The next 100 years would bring the addition of ingredients like bicarbonate of soda, borax, glycerin, strontium, and chalk.¹⁹

The first mass-produced toothpaste in a jar (Colgate & Co.) arrived in 1873, and by 1892, toothpaste had been packaged in a tube.¹⁹ Toothpaste brands like Kolynos (for teeth that “gleam like pearls”), Ipana (for a “smile of beauty”), and Pepsodent (“you’ll wonder where the yellow went..”) joined Colgate as popular, well-known toothpastes through the early 1940s.²⁰ A monumental breakthrough that would revolutionize the utility of dentifrices was the incorporation of fluoride for the reduction of tooth decay in the mid 1950s. Researchers like Klein and Palmer²¹ and later Dean²² conducted epidemiological studies in the 1930s that confirmed that fluoride levels in water supplies were associated with a lower incidence of dental caries. The public health significance of this newfound revelation was high, given that the state of dental health in the US was described by some as “deplorable” at the inception of WWII.²³ Clinical exploration of fluoride’s topical benefits in a dentifrice would follow, although formulation would prove challenging (e.g., Bibby et al’s chalk-based paste that inactivated fluoride).²⁴ Then a team led by Dr. Joseph Muhler

at Indiana University – in conjunction with Procter & Gamble (P&G) – developed and clinically tested fluoride toothpaste which was shown to provide a mean caries reduction of 49% in children.²⁵ This first commercially successful fluoride dentifrice – Crest® with Fluoristan™ (1000ppm stannous fluoride) – was launched nationally in 1956, and was awarded the American Dental Association’s Seal of Approval in 1960.²⁶ Today there are about five major toothpaste manufacturers globally and numerous smaller distributors and private label makers. The extensive number of distinct dentifrices (brand, indication, size) available worldwide varies regionally and is ever-changing.

Toothpaste Formulation Basics

den-ti-frice | \ 'den-tə-frəs \

Definition of dentifrice

: a powder, paste, or liquid for cleaning the teeth

Source: [Merriam Webster](https://www.merriam-webster.com/dictionary/dentifrice).

A quick internet search returns some articles asserting that **a toothpaste is a toothpaste**. It is true that most marketed dentifrices are composed of a core set of base ingredients that are combined to make dentifrice the entity we recognize today. These inactive (non-therapeutic) additives function as cleaners, stabilizers, or give esthetic benefits, and typically include:

- **Abrasives Why? Cleaning.** To aid the toothbrush in mechanically removing food debris, surface stains and dental plaque, an abrasive system is utilized. Commonly used abrasives are hydrated silicas, calcium carbonate, sodium bicarbonate, alumina, phosphate salts, and others.¹⁹ As opposed to the extremely harsh abrasives in use prior to the mid-1900s which have been abandoned for safety reasons, modern day dentifrice abrasives are mild and safe for frequent, long-term use, and ADA-accepted toothpastes must meet the International Standards Organization (ISO) requirement of having an RDA (relative dentin abrasivity) score of 250 or less.^{27,28}
- **Water Why? Solvent.** The humectants (see below) and water collectively make up
- **Humectants Why? Prevent drying.** To keep the solvent (usually water) in the toothpaste from drying out, humectants like sorbitol, glycerin, and propylene glycol are added to bind it. They additionally aid in keeping a smooth consistency and flow from the tube and can serve as preservatives.¹⁹
- **Binders/thickening agents Why? Add body, prevent separation.** Natural gums like xanthan, carboxymethyl cellulose carbomers, or synthetic celluloses are added, which swell when they contact water to give bulk and texture, and to stabilize the formulation by stopping the solid and liquid phases of the paste from separating.¹⁹ They contribute to the familiar consistency of dentifrice in appearance and mouthfeel, and facilitate its easy flow onto the toothbrush.
- **Surfactants Why? Foaming.** The characteristic foaming of toothpastes is enabled by surfactants (detergents), the most common being sodium lauryl sulfate (SLS). These multi-factorial excipients also assist in cleaning, as well as the stability of the emulsion via preventing flavor oil separation with the dentifrice.^{19,29}
- **Buffers Why? pH.** To ensure a toothpaste remains stable and is performing as intended (e.g., for fluoride bioavailability), buffers are added for pH constancy. Pyrophosphates, sodium citrate, and trisodium phosphate are examples.
- **Flavoring, sweeteners, colors Why? Taste and esthetics.** Peppermint, menthol, xylitol, sorbitol, and sodium saccharin are



Figure 2. Original Crest toothpaste, with the ADA Seal of Acceptance.

all examples of flavors and sweetening agents that are incorporated to give fresher breath and a desirable taste and brushing experience. Sweeteners are non-carries promoting. Added pigments/dyes give visual interest, and ingredients such as titanium dioxide lends opacity.^{19,29}

- **Specialty ingredients Why? Natural products interest.** Recently, specialty ingredients that may appeal to those interested in products viewed as natural-friendly have been incorporated into some toothpastes. Some examples include hemp/CBD, coconut oil, and tea tree oil.

Putting it all Together: Formulation Chemistry

If most toothpastes begin with essentially a similar compilation of the excipients described above, combining them into a dentifrice would presumably seem clear-cut. If toothpaste “recipes” were printed in cookbooks, however, the required skill level would be labeled:

Highly Advanced. Dentifrice formulation is known to be a complex, sophisticated process requiring scientific expertise from a team of individuals with specialized knowledge in their respective fields to determine the exact ingredient combination and proportions and ensure a final manufactured superior product that that is: 1) safe and efficacious; 2) esthetically desirable; and 3) stable and 4) bioavailable. The specific form (paste or gel) and choices in packaging delivery modalities (e.g., pumps, tubes, dual-chamber reservoirs) also have important implications for aggregate stability and efficacy. Mastery of each step in the processing method must be perfected in dentifrice manufacturing for a superior product, e.g., rheology optimization, to ensure the toothpaste disperses from the tube easily but is not too runny.

Individual ingredients may interact with and inactivate the therapeutic ingredients, so compatibility of the components is of paramount importance to dentifrice formulators. For example, the benefits of certain actives can be reduced or nullified by water. Abrasive ingredients can potentially hinder the activity of other components (e.g., sodium hexametaphosphate). Meticulous laboratory research – followed typically by



Source: [Unsplash.com](https://unsplash.com)

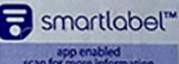

in situ and/or *in vivo* clinical investigations – are therefore needed to verify the final effectiveness and esthetic acceptability of newly formulated toothpastes.

Even something as seemingly straightforward as flavoring for a new toothpaste formulation can require an in-depth, multi-step process. Bankova et al. describe an example of the complexity in the development of new Colgate dentifrice variants, where the goal was to “...mask the unpleasant astringency and metallic off notes of the base ...” [and create] “...an appealing taste which pleases global consumers” to drive compliance.³⁰ Stability evaluation was done with accelerated aging of samples subsequently analyzed by gas chromatography mass spectrometry. This was followed by organoleptic assessment for taste acceptability by a flavor expert. Next, custom-made flavors were developed, but certain flavor molecules were unstable in the presence of the zinc and arginine active ingredients. Ultimately, stable flavoring agents were identified and “their consumer appeal and acceptance were validated with monadic identified product tests.”³⁰

What other challenges must be met? For manufacturers introducing a new toothpaste, successful formulation is achieved via an interdisciplinary, careful testing process including toxicology/safety analyses, *in vitro* proof of concept evaluations, and stability verification. Where American Dental Association (ADA) approval and/or a New Drug Application (NDA) will be sought, controlled clinical investigations and other regulatory procedures may be also required.

NEW INFORMATION & DIRECTIONS

Drug Facts Active ingredient Stannous fluoride 0.454% (0.15% w/v fluoride ion)	Purposes Anticavity, Antigingivitis, Antisensitivity	Drug Facts (continued) • builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact
Uses <ul style="list-style-type: none"> • aids in the prevention of cavities • helps prevent gingivitis • helps interfere with harmful effects of plaque associated with gingivitis 	Warnings When using this product for sensitivity, do not use longer than 4 weeks unless recommended by a dentist. Stop use and ask a dentist if the sensitivity problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.	

Drug Facts (continued) Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. Stop use and ask a dentist if <ul style="list-style-type: none"> • gingivitis, bleeding, or redness persists for more than 2 weeks • you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs of periodontitis, a serious form of gum disease. Directions <ul style="list-style-type: none"> • adults and children 12 years of age and older: apply at least a 1-inch strip of the product onto a soft bristled toothbrush. Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist. Make sure to brush all sensitive areas of the teeth. • do not swallow. • children under 12 years of age: consult a dentist. 	 app enabled scan for more information  0 35000 45987 9
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Drug Facts (continued) Other information <ul style="list-style-type: none"> • products containing stannous fluoride may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist. • this Colgate product is specially formulated to help prevent staining. 	Drug Facts (continued) Inactive ingredients water, sorbitol, hydrated silica, glycerin, PEG-12, tetrasodium pyrophosphate, sodium lauryl sulfate, flavor, microcrystalline cellulose, sodium citrate, zinc phosphate, cellulose gum, sodium saccharin, cocamidopropyl betaine, propylene glycol, xanthan gum, citric acid, sucralose, titanium dioxide
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SENSITIVITY RELIEF

PROTECTS TEETH, TONGUE, CHEEKS & GUMS

NET WT 1.4 OZ (39.6 g)

Total^{SF}
WHOLE MOUTH HEALTH

WHITENING
Paste

NEW ACTIVE INGREDIENT
STANNOUS FLUORIDE

Crest PRO HEALTH

GUM DETOXIFY™
Gentle Whitening
Neutrizes plaque bacteria even around the gum line

CLINICALLY PROVEN HEALTHIER GUMS

NET WT 4.1 OZ (116 g)

1. Neutrizes harmful plaque bacteria even around the gum line

2. Activated foam sweeps out bacteria in hard to reach places

3. Gently cools gums during brushing

ADA
• helps prevent cavities
• helps prevent gingivitis
• helps prevent plaque bacteria from building up
• helps prevent or reduce enamel erosion from dietary acids

Drug Facts Active ingredient Stannous fluoride 0.454% (0.14% w/v fluoride ion)	Purposes Anticavity, Antigingivitis, toothpaste	Drug Facts (continued) Directions <ul style="list-style-type: none"> • adults and children 12 yrs. of age and older: brush teeth thoroughly, preferably after each meal or at least twice a day or as directed by a dentist or physician. • do not swallow • children under 12 yrs. of age: ask a dentist Other information <ul style="list-style-type: none"> • products containing stannous fluoride may produce surface staining of the teeth • adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist • this Crest is specially formulated to help prevent staining • see your dentist regularly
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Drug Facts (continued) Inactive ingredients water, sorbitol, hydrated silica, sodium lauryl sulfate, carboxymethylcellulose, flavor, sodium gluconate, xanthan gum, zinc citrate, sodium chloride, sodium saccharin, sodium hydroxide, sucralose, titanium dioxide	Questions? 1-800-584-4158  www.pg.com www.crest.com DIST. BY PROCTER & GAMBLE CINCINNATI, OH 45202 © 2019 P&G Patents: www.pg.com/patents
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Toothpaste as a Vehicle

Merriam Webster defines **vehicle** as an agent of transmission: a carrier. A bus is a vehicle for transporting persons across a route and delivering them to a destination. In the world of pharmaceuticals, drug delivery systems can be utilized as vehicles to transport treatments (e.g., encapsulated drugs in carrier vehicles like liposomes activated by focused ultrasound),³¹ often in ways that are less harmful than systemic drug administration and more targeted to the area of concern.

Toothpastes are ideal and cost-effective vehicles. They can readily deliver oral therapeutic ingredients, and they are already in nearly universal daily use. If all that was available were basic pastes with only the core inactive ingredients listed in the previous section of the course, patients would no doubt use them versus 'dry brushing'.^{15,16} However, they would be missing out on the full potential and ultimate value of a dentifrice: its utility as a delivery mechanism for therapeutic ingredients that can significantly impact their dentition and oral health by preventing disease, treating conditions, and/or providing cosmetic agents



Source: [Every Home Should Have One, 1970.](#)

like whiteners that consumers are increasingly seeking.

Fluoride was the first – and remains the classic – example of harnessing the power of toothbrushing with toothpaste to serve as an oral health active agent delivery system. Unlike other challenges to sustain behavior modification or habit formation strategies, nearly everyone is already using toothpaste – from children through seniors – and thus it is the ideal vehicle to deliver topical fluoride on a routine basis. No added product or step is needed.

Toothpaste Selection Considerations

The oral health products market is dynamic, and there may be dozens of distinct toothpaste options (excluding children's pastes) available to the consumer at any given time. Pinpointing the patient's individual oral hygiene needs, challenges, and personal likes/dislikes – together with an understanding of the mechanisms of action of therapeutic ingredients, product claims, and supporting clinical research – can go a long way in sorting through the choices and finding an optimal match.

Figure 3 provides one framework for consideration in selecting a dentifrice from the myriad of available options, based on individual oral health needs and preferences.

Selection Criteria #1: Fluoride?

#1 – A key place to begin is to identify whether the chosen dentifrice will contain fluoride.

The Case for Fluoride in Dentifrice

Dental caries is the most widespread chronic disease in the world.^{32,33} Tooth decay is initiated by acid production generated from sugar breakdown/metabolism (often in hard-to-clean tooth pits and fissures and interproximal crevices), and progresses over time to ever greater levels of severity unless it is detected and treated in its early stages. Over the past few decades there has been progress in the fight against caries – especially in tandem with fluoride exposure. A stark decline in the mean number of decayed, missing, or filled permanent teeth (DMFT) in 12-year-old U.S. children from 1967-1992 shows a clear association between an increase in those drinking fluoridated water (Figure 4). Importantly, fluoride dentifrice as topical application became commonplace during this timeframe as well.

Despite this, an estimated 35% of the global population (2-4 billion people) has untreated tooth decay in permanent teeth, varying by region and socioeconomic status (Figure 5).^{32,35} A systematic caries epidemiological review

concluded that “dental caries is a lifelong disease,” and while prevalence has declined in some age cohorts, there has been an increase in elderly persons having more teeth, root caries, and an average second prevalence caries “peak” at age 70, thus keeping the burden of disease high.³⁴ Dental caries constitutes one of the two leading causes of tooth loss, and is a major negative determinant of quality of life when it results in pain, eating difficulties, and missed school/work.^{33,35}

The multifactorial etiology of caries involves the interplay between sugars from ingested food, the bacterial biofilm in dental plaque, and the integrity of the tooth surface.³⁶ The importance of pH from ingested food and beverages in the modern diet also plays a role in rate of loss of tooth mineralization. The first two causative factors are theoretically modifiable; e.g., dietary sugar consumption can be reduced to lower acid attacks to tooth enamel, and good oral hygiene via diligent daily toothbrushing helps control the biofilm microbiota. In reality, however, sugar intake can be challenging to modify, especially given the high availability and consumption of sugary foods and drinks.^{35,37} Similarly, challenging is achieving complete oral hygiene plaque removal, which research has shown is infrequently achieved.^{38,39}

The third caries causative factor – the integrity of the tooth surface – may arguably represent the easiest intervention in the prevention of dental caries with use of a fluoride dentifrice. The mineral fluoride (from the trace element fluorine) is found in abundance in the environment and in natural water sources. One of the greatest public health achievements of the 20th century was the recognition of fluoride as a significant contributor to the strengthening of tooth enamel and reduction of caries risk, first systemically via water fluoridation programs, and then as a topical agent delivered most commonly through fluoridated toothpastes or professional topical application.⁴⁰

How Fluoride Works

When acids are produced by the metabolism of carbohydrates by cariogenic bacteria, the pH of the plaque biofilm

TOOTHPASTE SELECTION CONSIDERATIONS

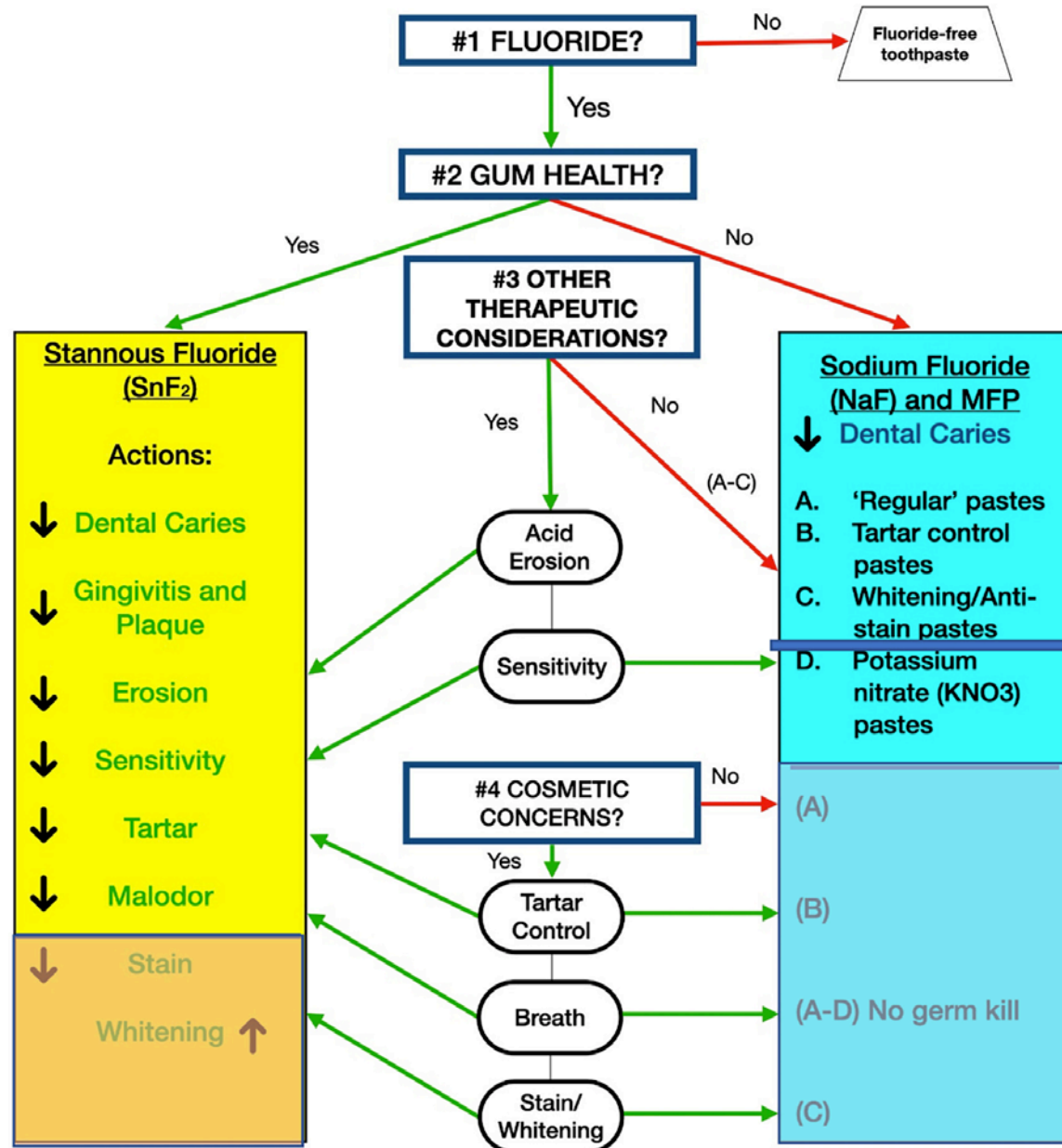


Figure 3. Toothpaste Selection Considerations.

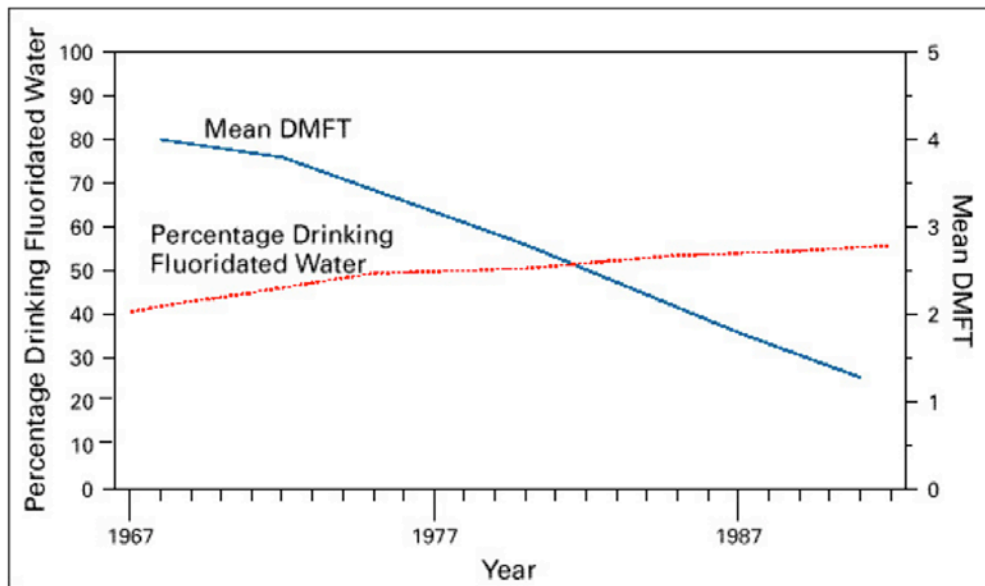


Figure 4. The Association between Fluoridated Drinking Water and Dental Caries.³⁴ Percentage of population residing in areas with fluoridated community water systems and mean number of decayed, missing (because of caries), or filled permanent teeth (DMFT) among children aged 12 years - United States 1967-1992.

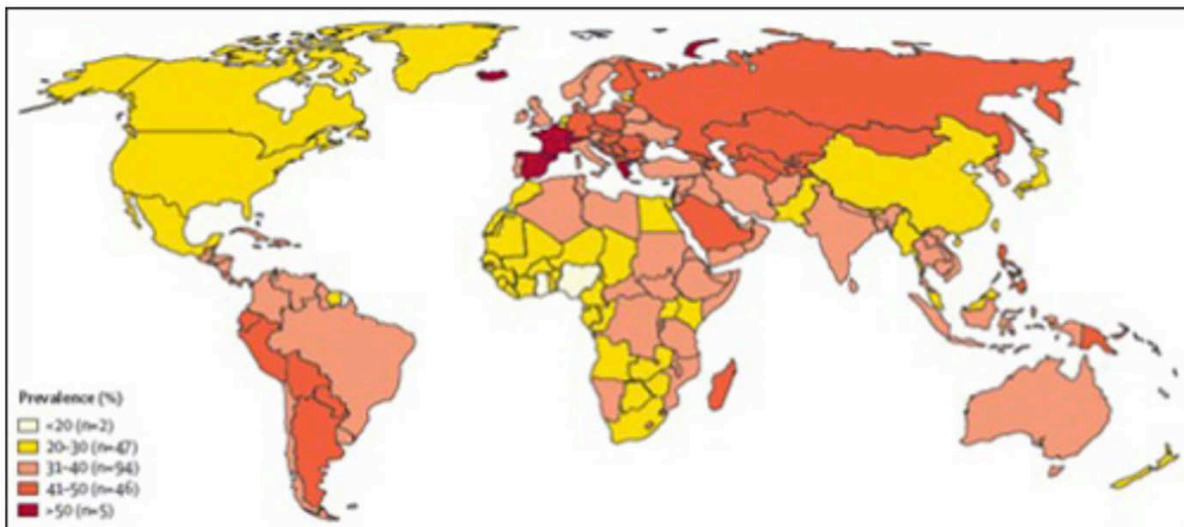


Figure 5. Estimated Global Prevalence of Untreated Dental Caries in Permanent Teeth for 2017.³²

decreases. When it drops below 5.5, the result is enamel demineralization: the dissolution of tooth enamel hydroxyapatite (calcium and phosphate ions). Remineralization occurs when the minerals are reincorporated from an elevation of pH via buffering from saliva. If demineralization/remineralization successions are ongoing and there is no intervention, a subsurface caries lesion is the

outcome. Cavitation, and even potential pulp involvement and tooth loss can follow.^{36,41,42}

Topical fluoride deters demineralization and enhances remineralization; when it is present in saliva and dental plaque, it replaces hydroxyapatite with fluorapatite, which is more resistant to dissolution in the presence of cariogenic acid challenges. The result is

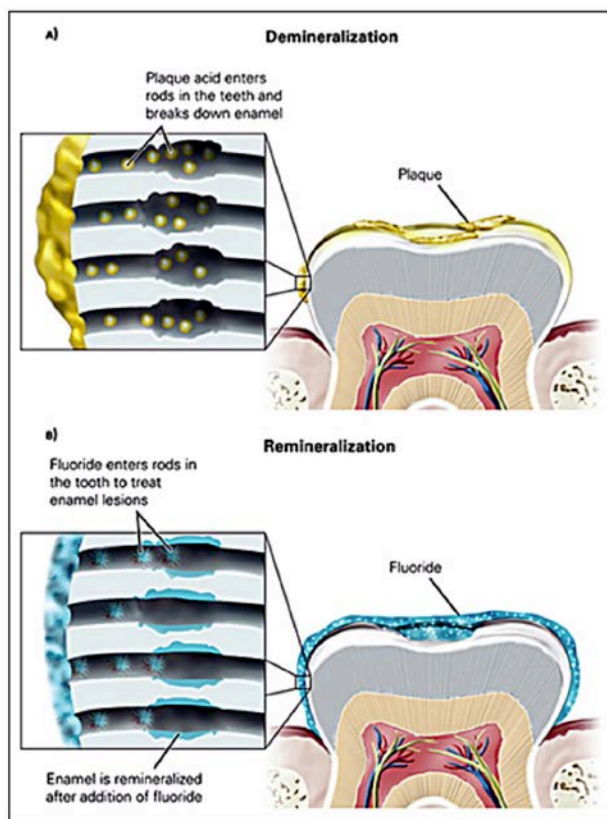


Figure 6. Demineralization/Remineralization. (A) Plaque acids cause a demineralized, sub-surface lesion. (B) Fluoride treatments remineralize the lesion with a more acid resistant fluorapatite mineral.

that incipient carious lesions are prevented or their growth reduced by the anticaries agent fluoride.^{43,44}

In a comprehensive evidence-based review of fluoride vehicles and strategies, O'Mullane et al. concluded, "Fluoride toothpaste is now the most widely used method for maintaining a constant low level of fluoride in the oral environment, and its widespread use is considered to have played an important role in the decline in dental caries in industrialized countries in recent decades."⁴⁵ Fluoride incorporation in marketed dentifrices has become the norm, with 95% of commercially available toothpastes in many countries now containing it.⁴⁶ In the US, three different fluoride compounds are approved for usage in marketed dentifrices today as per the US monograph system; these three are also the most frequently used globally: sodium

monofluorophosphate ($\text{Na}_2\text{PO}_3\text{F}$ "MFP"), sodium fluoride (NaF), and stannous fluoride (SnF_2). When formulated in a toothpaste correctly in the right concentration (1000-1500 ppm for over the counter pastes) and bioavailability, all have been shown in clinical trials to significantly reduce dental caries compared to a negative control.^{47,48} Dental professionals generally recommend the twice daily use of an ADA-approved fluoride toothpaste.

Choosing a Fluoride-free Dentifrice: Why?

In recent years a niche segment of dentifrices that do not contain fluoride has emerged (e.g., Tom's of Maine®, Hello®, Burt's Bees®). Those using these products may have an interest in "natural" personal care products and perceive fluoride to be an unnatural chemical, and/or have a concern about the safety of fluoride.⁴⁹ A large body of research has concluded that fluoride – which is naturally found in most large bodies of water – is safe at the appropriate concentrations that aid in caries prevention.⁴⁵ The ADA only provides its seal of acceptance to toothpastes containing fluoride, based on its demonstrated anti-caries effectiveness.⁵⁰

Selection Criteria #2: Gingivitis Prevention/Reduction?

#2 – Another major consideration is the need for gingivitis prevention/reduction.

Figure 3 highlights a second key decision point in selecting a toothpaste: Is optimizing gingival health via the prevention or reduction of gingivitis and bleeding relevant to the patient? For many, the answer will be **yes**.

You have seen the commercials: A drop of blood is shown in a sink near a toothbrush, or a dental professional in a white coat comments that bleeding after oral hygiene is never normal. Despite strong messaging to the public about the link between bleeding gums and gingivitis with the origin being unremoved plaque, unawareness of the link, or belief that it is normative and not a significant concern, is still prevalent.⁵¹ Regardless, epidemiological assessments show gingivitis and bleeding gingiva *are* common.



Source: Crest.com. *Quick Facts About The Plaque on Your Teeth*.

Gingivitis has pervasive prevalence estimates ranging from one-half to almost nine-tenths of adults impacted.^{52,53} If not arrested, susceptible individuals will see gingivitis progress to periodontal disease with the potential for alveolar bone and tooth loss. About 42% of American adults have periodontitis according to the CDC's National Health and Nutrition Examination Survey (NHANES) survey,⁵⁴ and an estimated 743 million people, worldwide, suffer from the most severe form (Figure 7).⁶ In adults between 65 and 74 years of age, about one-third are edentulous primarily due to periodontal disease.⁶

Additionally, robust associations with systemic disease involvement like cardiovascular disease and diabetes – either directly with bacteria entering the bloodstream or via the

resultant inflammation – are being increasingly substantiated.^{55,56} With the potential of tooth loss to adversely affect chewing function and quality of life, and the whole-body common inflammatory pathway threat, the FDI has warned that periodontitis "...represents a major global oral disease burden with significant social, economic and health-system impacts."^{6,32}

Harald Löe's oft-cited, classic experimental gingivitis study in 1965 convincingly established evidence of the plaque/disease connection; oral hygiene was withheld for three weeks in volunteers with previously healthy gingivae. Consequently, generalized gingival inflammation was observed in 10 to 21 days as bacterial counts and pathogenicity in the now heavy plaque colonizing the teeth grew dramatically with time.⁵⁷

Importantly, these sequelae were reversible. Löe remarked, "When good oral hygiene was reinstituted, the original sparse microflora was reestablished and the inflamed gingiva reverted back to normal."⁵⁸ Future similar experiments would confirm these findings.⁵⁹⁻⁶¹

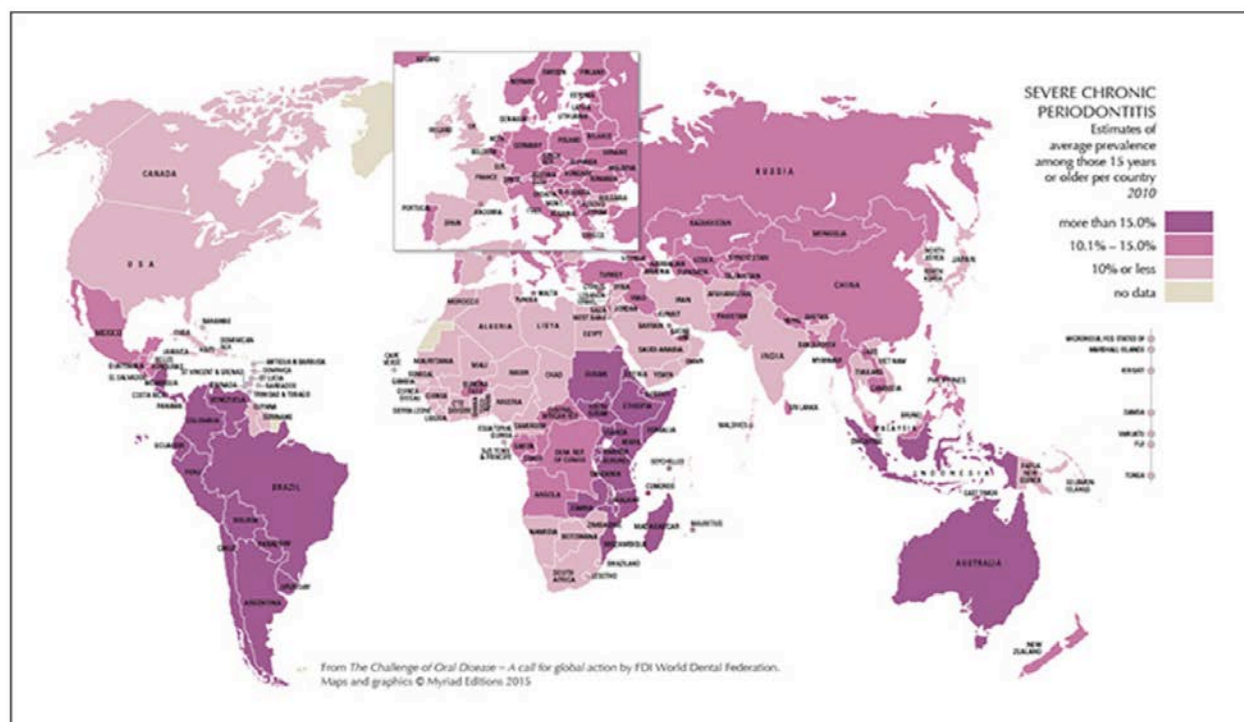


Figure 7. Estimated Global Prevalence of Severe Periodontitis.

Source: [The Challenge of Oral Disease – A call for global action by FDI World Dental Federation](http://TheChallengeofOralDisease.com) Myriad Editions. 2015.

Why then, is mechanical home oral hygiene (toothbrushing plus interproximal cleaning) not the end all for staving off gingivitis? For a minority of motivated, conscientious patients, meticulous daily plaque removal – regardless of what dentifrice is used – could be sufficient to keep the periodontium disease-free. But research (including video-taped assessments) has generally shown that many individuals are not sufficiently committed or do not have the manual dexterity or skill to remove the volume of plaque (including in the higher risk gingival margin and approximal regions) required to prevent gingival inflammation with the standard manual toothbrush. They are therefore at risk of developing gingivitis, and subsequently periodontitis if they are susceptible. Consider the following research findings in Table 1.

These realities provide context for the high global prevalence of gingivitis and periodontal disease and the need for additional treatment

modalities. In response to the challenge, some toothpaste manufacturers have harnessed the utility of toothbrushing with dentifrice as a vehicle for oral health chemotherapeutics in the same way as fluoride for caries prevention: an anti-plaque/anti-gingivitis therapeutic agent has been incorporated to optimize gingival health **alongside** routine mechanical oral hygiene practices like manual or power toothbrushing and flossing. Again, this provides the benefit of piggybacking upon an already-utilized practice – toothbrushing – without requiring additional steps and products.

Anti-gingivitis Active Ingredients

To date, two antimicrobial, gingivitis-fighting agents have been successfully added to toothpastes to target plaque and gingivitis: triclosan and stannous fluoride. **Triclosan**, a broad-spectrum antimicrobial, acts by disrupting the cytoplasmic membrane.⁷³ Triclosan was the active ingredient used in Colgate Total® for many years until the product



Figure 8. Recognizable signs of established gingivitis include red, edematous, bleeding gums.

Table 1. Self-care Plaque Removal Effectiveness.

- Few individuals use dental floss routinely and about one-third never floss.⁶²⁻⁶⁴
- A typical brushing session removes less than 50% of all plaque.⁶⁵
- The longer the brushing session, the more plaque is removed, yet many don't brush long enough and overestimate how long they brushed.⁶⁵⁻⁶⁹
- Many don't follow through long-term with the brushing methods they were professionally instructed in.⁷⁰
- Some individuals appear to be hypersensitive to lesser amounts of plaque based on unique host factors.^{71,72}

was reformulated and triclosan was replaced with stannous fluoride in 2019. Triclosan is no longer incorporated in toothpaste formulations following potential safety concerns.⁷⁴

Stannous fluoride (SnF₂) is distinctive among the three fluorides shown in Figure 3 in that it has multiple functions beyond caries prevention. Notably, stannous fluoride also is a clinically proven effective antimicrobial: three systematic reviews/meta-analyses have found significant superior gingivitis and gingival bleeding reductions compared to various toothpaste controls in long term clinical trials.⁷⁵⁻⁷⁷ The bacteriostatic and bactericidal mechanisms of SnF₂ do not fade quickly after brushing; activity can be present up to 12 hours later.^{78,79} Subgingival plaque sampling using P&G formulations in a clinical trial detected SnF₂ anti-inflammatory activity following brushing up to 4 mm below the gumline.⁸⁰ It has long been known to improve gingival health via decreasing the growth and adhesion of bacteria, as well as reducing acid production and toxic metabolic products that are factors in gingival inflammation and bleeding.^{78,79,81} More recently, research has demonstrated that SnF₂ in a stabilized bioavailable dentifrice formulation additionally interacts directly with bacterial endotoxins to reduce pathogenicity, i.e., it modulates the process of gingival inflammation by binding pathogens to blunt the immune response.⁸¹⁻⁸⁸

Formulation acumen is critical when it comes to stannous fluoride toothpastes, because SnF₂ will not have optimum bioavailability if the dentifrice technology does not account for various ingredient combinations which can impede its effectiveness or hinder stability, substantivity, or esthetics.⁸⁹⁻⁹² At least three dentifrice manufacturers now offer stannous fluoride plaque- and gingivitis-fighting toothpastes, each with 0.454% stannous fluoride but differing SnF₂ systems. One dental professional shared the opinion in an online dentifrice review, ***“Stannous fluoride is stannous fluoride is stannous fluoride.”***⁹³ However, the magnitude of anti-gingivitis benefits for the marketed SnF₂ dentifrice examples listed below can vary based on the specific amalgamation of the components in

the formula, and the interventions taken to ameliorate factors such as oxidation and SnF₂ deactivation.^{92,94} These affect the stannous fluorides’ ability to be bioavailable to penetrate the biofilm and neutralize toxins to exert the desired therapeutic effect.

The Crest® brand has a long history of utilizing stannous fluoride (the original 1960s Crest featured Fluoristan®) for both caries prevention and gum health benefits. The formulation has been optimized over time to increase stability and efficacy with maximally compatible abrasive systems to provide for maximum bioavailability for anti-plaque and gingival health benefits.^{90,91} Crest ProHealth and Crest Gum Detoxify contain 0.454% bioavailable stannous fluoride with citrate. The manufacturer cites over 100 SnF₂ clinical trials demonstrating significantly greater anti-plaque and/or anti-gingivitis benefits for the gluconate-chelated SnF₂ bioavailable family of toothpastes compared to other dentifrices.⁹⁵ A recently published meta-review of 18 randomized controlled clinical trials of almost 3000 subjects comparing SnF₂ bioavailable stannous fluoride with the same formulation to toothpaste controls concluded that SnF₂ reduced the average number of bleeding sites by 51% compared to non-antimicrobial dentifrices.⁹⁶ In addition, participants with gingivitis had 3.7 times better odds of moving to “generally healthy” status (<10% bleeding sites) when using the SnF₂ dentifrice compared to those using a negative control. Most recently in a 3-month randomized, controlled clinical trial, 3/4 of subjects brushing with a ProHealth SnF₂ formulation transitioned from generalized/ localized gingivitis to generally healthy, compared to no subjects in another marketed 0.454% SnF₂ control group.⁹⁴ The former provided 78% fewer bleeding sites relative to the comparator 0.454% SnF₂ dentifrice at Month 3.

Another recent Crest formulation change includes the introduction of the amino acid glycine. This unique amino acid further stabilizes the stannous formulation, delivering 180% more tin delivery into the biofilm than a stannous positive control without glycine, allowing for deeper penetration into the biofilm

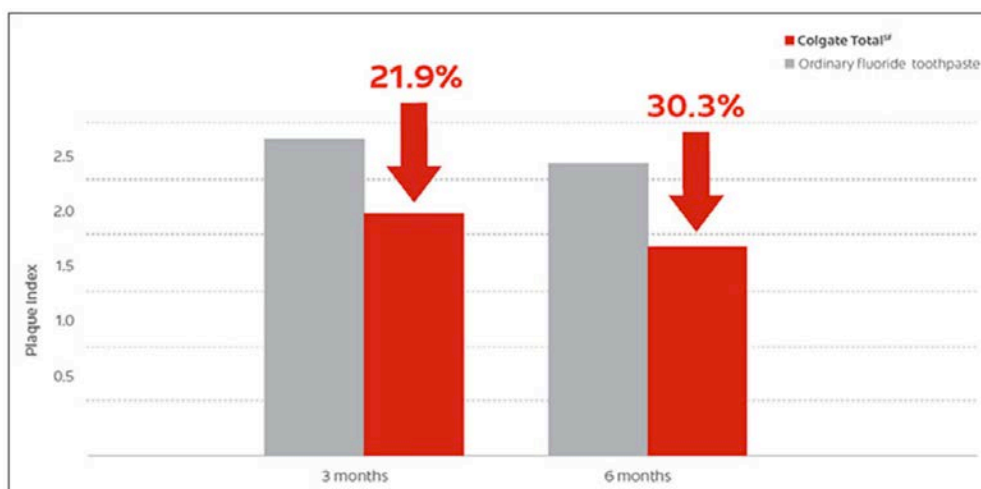


Figure 9. Plaque reduction of a 0.454% SnF₂ dentifrice stabilized with zinc phosphate versus a negative control.

Source: [Colgate Professional](#), [Colgate Total^{SE}](#)

and allowing access to neutralize the most virulent toxins at the depth of the biofilm.⁹⁷

Colgate Total products have been reformulated with 0.454% stannous fluoride. The new SnF₂ multi-benefit formulation – in development for 10 years – is a patented inactive zinc phosphate system that enables SnF₂ to remain stable and active in delivering its intended benefits.⁹⁸ Two published six-month clinical studies demonstrated that Colgate Total was superior to a regular fluoride dentifrice⁹⁹ (Figure 9), and comparable to another marketed 0.454% SnF₂ dentifrice¹⁰⁰ for the reduction of plaque and gingivitis.

GlaxoSmithKline's (GSK Consumer Healthcare) Parodontax™ was available through the 1990s as an herbal/sodium bicarbonate formulation, but was recently reformulated and relaunched with 0.454% stannous fluoride as the active ingredient, stabilized in a non-aqueous base, and including sodium tripolyphosphate.¹⁰¹ In a 6-month published clinical trial, using Parodontax resulted in a 40% reduction in gingival bleeding versus baseline compared to an MFP negative control toothpaste.¹⁰² GSK also manufactures Sensodyne Complete Protection®, which contains the same 0.454% SnF₂ technology as Parodontax. This dentifrice was found in a 6-month clinical trial to provide 35.5% significantly better gingival bleeding

site reduction compared to an MFP negative control toothpaste.¹⁰³

Choosing Something Other than an Antimicrobial Dentifrice: Why?

If the risk of gingivitis for the average patient is nearly 100% and the evidence for the efficacy of the adjunctive use of stabilized stannous fluoride dentifrices in the prevention and reduction of disease is convincing, why *wouldn't* someone choose to use one? For some, there may be a concern that stannous fluoride will get in the way of tooth whitening. First generation SnF₂ products were indeed sometimes associated with extrinsic stain. This issue has been successfully overcome via formula stabilization and new abrasive systems and should no longer be a reason to shy away from SnF₂ products. Today, stabilized SnF₂ dentifrices have been shown in clinical trials comparing them with non-SnF₂ control pastes to not contribute to surface stains, and in fact may whiten teeth.^{90,98}

On the right side of Figure 3 are the non-SnF₂ fluorides in common use today: sodium fluoride (NaF) and sodium monofluorophosphate (MFP). Both have well-confirmed evidence of anti-caries efficacy.^{47,48} The most basic NaF and MFP anti-caries toothpastes – and likely at the lowest price point – are those which contain no other active

ingredients and claim no other therapeutic or unique cosmetic benefits. Currently marketed examples include Colgate Cavity Protection, Crest Cavity Protection, and Aquafresh® Cavity Protection.

Selection Criteria #3: Other Therapeutic Conditions

#3 – What other conditions need to be addressed therapeutically?

A third decision point in the toothpaste selection process is to consider what other oral health conditions the patient may need to address. Beyond the “big two” (gingival/periodontal health and tooth decay), patients can be impacted by two other not-uncommon concerns: dentinal hypersensitivity and enamel erosion. Here again, dentifrice can serve as an easy-to-use vehicle to deliver therapeutic ingredients proven to protect against and reduce these issues with regular use.

Dentinal Hypersensitivity

*“Pain derived from exposed dentin in response to chemical, thermal tactile or osmotic stimuli which cannot be explained as arising from any other dental defect or disease.”*¹⁰⁴ Dentinal hypersensitivity is a common problem that may impact as many as 74% of adults at some point, and an even greater proportion of periodontitis patients.^{105,106} Exposed dentin can be the result of enamel loss (from physical or chemical sources), or from gingival recession that exposes the root.¹⁰⁷ This exposure results in sharp, transitory pain commonly in response to thermal (e.g., cold air), chemical, and tactile triggers. The condition is uncomfortable and can cause sufferers to avoid thorough toothbrushing or professional dental care for fear of pain.

Desensitizing agents that can be delivered via the dentifrice vehicle are an excellent first-line strategy for anti-sensitivity treatment. The two most commonly used agents are stannous fluoride (a third therapeutic benefit of SnF₂ beyond caries and gingivitis prevention) and potassium nitrate (KNO₃). The former, SnF₂, forms a smear layer that occludes dentinal tubes. Potassium nitrate acts by disrupting

the nerve impulse transmission to the pulp.¹⁰⁸ Two large meta-analyses of anti-sensitivity toothpastes with various agents have concluded that they provide significant benefits relative to a placebo, with the exception of strontium-based dentifrices.^{109,110}

When choosing an anti-sensitivity toothpaste, in the US and Canada, clinicians and patients can select from stannous fluoride options found in stabilized SnF₂ multi-benefit dentifrices. Examples include: Colgate Total, Crest Gum and Sensitivity, Parodontax, and Sensodyne Sensitivity and Gum. An advantage of the SnF₂ paste choice for dentinal hypersensitivity is that SnF₂ provides other concurrent benefits (e.g., anti-caries, anti-gingivitis, anti-erosion) in one product.

Per Figure 3, dentinal hypersensitivity sufferers also have the option of sodium fluoride-based toothpastes with 5% potassium nitrate; some marketed choices include: Sensodyne Fresh Mint; Colgate Sensitive, Crest 3D White Whitening Sensitivity Care, and Aquafresh Sensitive.

Dental Erosion

When the enamel surface is pathologically challenged by acidic insult and demineralized, **erosive toothwear** is the result. This is different from dental caries because dental erosion is generated by non-bacterial acids (often dietary) that can dissolve the fluorapatite structure.¹¹¹ This condition has linkages to dentinal hypersensitivity due to acid exposure of dentin tubules and similar estimated prevalence rates.¹¹² As with hypersensitivity, the exact numbers of individuals with erosive toothwear is difficult to specify with exactness but is estimated to be high and appears to be growing – especially in younger adults – because of high dietary acid exposure, e.g., erosive sugary energy drinks, sports beverages, and sodas.¹¹³⁻¹¹⁶ It is important to strive for erosion *prevention*, because the condition is often not diagnosed until a later stage, and lost tooth structure is not reversible and thus costly to address via restorative dentistry.¹¹⁷

To that end, one of the three commonly utilized fluoride agents in dentifrices – stannous fluoride – has been shown to be uniquely

advantageous in preventing erosive toothwear. The mechanism of action is the deposition on the enamel pellicle surface of an acid-resistant protective barrier layer.¹¹⁸ *In situ* investigations of bioavailable SnF₂ exposure have found up to 80% greater enamel erosion protection benefits compared to a control.¹¹⁹⁻¹²¹

In seeking a toothpaste with SnF₂ anti-erosion benefits, the choices will be the same as those described previously in the course for other conditions where a stabilized stannous fluoride multi-indication dentifrice has demonstrated proven therapeutic benefits (caries, gingivitis, dentinal hypersensitivity). See also Figure 3.

Selection Criteria #4: Cosmetic Concerns/Goals?

#4 – Are there cosmetic concerns or goals?

After determining whether a therapeutic dentifrice is desired or not, another important consideration is related to any esthetic/cosmetic concerns or wishes. These commonly include whether an individual forms calculus, has oral malodor, or wants to remove dental stain and whiten the teeth. See Figure 3.

Tartar Control

Everyone forms dental plaque, and half to almost 100% of adults also are prone to supragingival dental calculus.^{121,122} Where dental calculus forms and in what quantities differs from person-to-person, with certain regions (buccal surfaces of the maxillary molars and the lingual surfaces of the mandibular anterior teeth) universally being the most susceptible to build-up.¹²³ Tartar formation is the result of salivary calcium and phosphate absorption in plaque, followed by a crystallization process, and ultimately the formation of hardened crystalline matrix-like mineral/microorganism aggregates.^{123,124} These tenacious accretions can be removed only by a professional prophylaxis and not by the patient.

Dental calculus might be viewed as a hybrid between a therapeutic issue and a cosmetic complaint. As an oral health concern, its



presence at the gumline has the potential to physically impede thorough oral hygiene. In addition, mature tartar's porous structure may indirectly contribute to gingival disease, in that it can act as a trap for additional dental plaque accumulation adjacent to the gingiva where gram-negative pathogens can proliferate.^{122,123} When patients think of calculus, however, it's likely because they've noticed the yellowish, unattractive deposits. Tartar deposits readily harbor extrinsic stains, often leading to a cosmetically displeasing result even on facial surfaces if not prevented or removed. While prophylaxis can remove unsightly calculus, it will begin to form again and reach pre-prophylaxis levels without some type of intervention. Heavy and widespread calculus can necessitate multiple professional scaling sessions, which is often objectionable to the patient.

Fortunately, scientific progress with dentifrice formulation yielded a convenient and clinically proven strategy for dental calculus mitigation: 'tartar control' toothpastes. The abrasive systems in toothpaste help to prevent stain accumulation and remove plaque preventing calculus, however advances in chemistry allow the introduction of new ingredients. The intent of these products is to prevent or slow the crystallization of plaque with anti-calculus ingredients like zinc salts, pyrophosphate, and sodium hexametaphosphate.

Zinc salts inhibit crystal formation when included in dentifrices, and have been found to significantly reduce and even prevent calculus formation compared to regular dentifrice in clinical trials.^{123,125,126} Zinc citrate is the anti-calculus agent in 0.454% SnF₂ multi-benefit toothpastes like Crest ProHealth Clean Mint and Crest Gum and Breath Purify

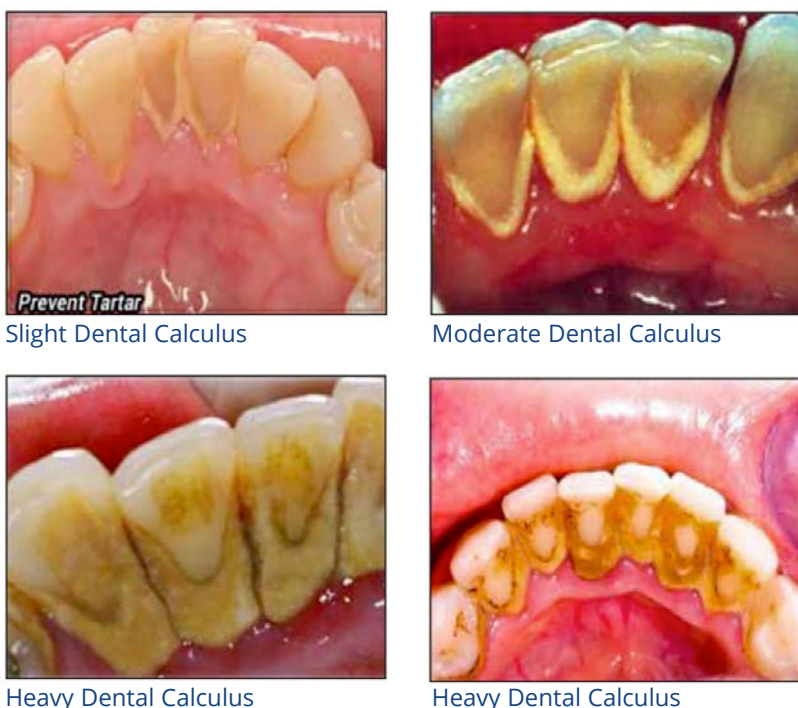


Figure 10. Stages of Teeth Tartar Formation.

Source: [dentalcare.com. Tartar on Teeth](http://dentalcare.com/Tartar-on-Teeth).

Healthy White. **Pyrophosphates** have been utilized widely for clinically proven tartar control, acting in toothpastes via mineral inhibition.^{123,126} Dentifrices currently incorporating pyrophosphates include the multi-benefit 0.454% SnF₂ pastes Colgate Total and Parodontax Whitening Complete Benefit, and the sodium fluoride-based Aquafresh® Ultimate White and Arm & Hammer Complete Care® dentifrices. The polypyrophosphate **sodium hexametaphosphate** (e.g., Crest ProHealth Advanced Whitening) also targets plaque calcification and has shown anti-calculus benefits in a dentifrice as high as 55% greater versus a regular dentifrice in clinical investigations.^{127,128} A small subset of individuals are sensitive to sodium hexametaphosphate; in this instance, another anti-calculus dentifrice with a different agent can be chosen.¹²⁵

Oral Malodor

Few conditions are as embarrassing and socially frowned upon as halitosis, and it is a common patient complaint. Transitory causes may include the consumption of pungent food,

or overnight 'morning breath' resulting from reduced salivary flow. Chronic oral malodor can be induced by systemic disease, but is more typically generated by intraoral causes, e.g., smoking, mouth breathing due to sinus conditions, regular pungent food consumption, and suboptimal oral hygiene. When dental plaque and food debris are not completely cleared from the tongue and difficult-to-reach areas of the dentition on a regular basis, gram-negative bacteria proliferate and putrefactive processes occur, with the corresponding release of volatile sulfur compounds (VSC). VSCs are exhaled and produce foul odors.^{129,130}

The strategy for reducing oral malodor caused by insufficient oral hygiene includes more frequent and efficacious toothbrushing and interproximal cleaning, tongue brushing, and treatment for periodontal disease if appropriate.¹³¹ Research has shown many patients can additionally benefit from adding an antimicrobial product to their daily oral hygiene regimen. Mouthrinse antimicrobial agents like cetylpyridium chloride (CPC) have

shown anti-malodor efficacy.¹³² However, many patients may lack motivation to utilize a mouthrinse faithfully together with toothbrushing. Antimicrobial dentifrices can alternatively provide an effective malodor-fighting mechanism in one step (Figure 3). Of currently marketed dentifrice antimicrobial agents, 0.454% stannous fluoride (e.g., in multi-benefit dentifrices Colgate Total, Parodontax, Crest Gum and Breath) has consistently demonstrated significantly superior malodor reduction (short-term and overnight) relative to negative controls with twice daily usage in controlled clinical investigations with stabilized SnF_2 .¹³³⁻¹³⁵

Flavoring agents in non-antimicrobial (NaF and MFP) toothpastes are another option for addressing oral malodor. Their breath-freshening effects, however, provide temporary masking of halitosis similar to the effect of breath mints, and do not treat the underlying etiology or provide the germ kill and more sustained breath protection benefits of antimicrobial dentifrices.

Stain Control/Whitening

The interest in tooth whitening has exploded, and it seems just about everyone wants a more attractive smile to feel their confident best, as seen by the popularity of cosmetic dentistry procedures (e.g., veneers; in-office bleaching) and at-home products like whitening strips. Tooth shade dulling and discoloration can be the consequence of natural aging wherein the enamel thins and becomes more translucent after years of wear, or from other intrinsic factors.¹³⁶ It can also commonly stem from extrinsic staining like that generated by smoking, dark beverages, and inadequate oral hygiene.¹³⁷

Fresh from a prophylaxis or bleaching treatment, patients will want to retain their whiter smiles. However, biofilm and dietary-driven (e.g., coffee and tea tannins) extrinsic stains tend to reaccumulate rapidly. Many seek out dentifrices formulated for stain removal and/or whitening as an affordable means of enhancing or maintaining their preferred shade. What exactly are 'whitening' toothpastes? These products typically contain

ingredients that work in one (or a combination of both) of the following ways: mechanical stain control and chemical stain control.

Mechanical Stain Control

Toothpaste abrasive systems are the foundation of a dentifrice's ability to physically remove extrinsic stains during brushing. As discussed in the What Exactly is Dentifrice? section, commonly used abrasives like hydrated silica, calcium carbonate, and sodium bicarbonate have been shown to be safe and effective in removing surface stains with adequate, regular toothbrushing.¹³⁸ See the sidebar Toothpaste Abrasivity and Safety for more information. Other ingredients can serve indirectly to augment the mechanical stain removal leading to whiter teeth. Tartar control agents like zinc citrate reduce calculus buildup which has a propensity to incorporate stain into its rough, porous structure.



[Click on image to view video online.](#)

Chemical Stain Control and Whitening

There are two potential mechanisms by which chemical agents in dentifrices lighten teeth. One means is oxidative via disruption of carbon bonds within the color-reflecting materials of stain to effectively lighten the stain for a whiter appearance.¹⁴⁰ **Hydrogen peroxide** is an example of an agent that works this way. Historically it has been challenging to formulate in a dentifrice and provide meaningful whitening efficacy at the customary 1% concentration and clinical trial effectiveness results have been mixed.¹⁹ Recently, however, toothpastes have been introduced with higher peroxide concentrations. Colgate Optic White became the first toothpaste to earn the ADA Seal of Acceptance in the home bleaching

Toothpaste Abrasivity and Safety

Toothpaste abrasives are clearly integral to effective cleaning, and patients are motivated to brush when they experience cleaner, smoother teeth and fewer surface stains from the mechanical polishing and stain lifting action of abrasives. But when selecting a toothpaste, how important is its RDA (relative dentin abrasivity) number? Does lower mean ‘better’ and safer to enamel?

A laboratory-confirmed limit of less than 1 mm of confirmed dentin loss for every 100,000 brushing strokes was the abrasive safety standard set decades ago, and became the basis for today’s industry-wide abrasivity testing methods.¹³⁹ It had been determined that over 90% of stain removal could be accomplished without higher levels of abrasivity in a toothpaste. In the 1970s an ADA-led group partnering with industry researched and developed the now standard RDA evaluation method. In 1980 in the anti-caries monograph, the FDA set a tooth wear limit for anti-caries dentifrices of 2.5 times the abrasiveness of the laboratory reference abrasives (e.g., ≤ 250), based on extensive real-life data and exaggerated usage by patients of varying ages, brushing styles, etc. Put another way, this limit provides assurance that usage of a toothpaste with ≤ 250 RDA won’t result in greater than 1mm of dentin wear and is safe for a lifetime of usage.¹³⁹

Importantly these laboratory methods are not, and weren’t intended to be, representative of real-life wear conditions. Toothpastes range in RDA values. Generally speaking, a higher abrasivity level dentifrice will remove more stain and enhance whitening and have a higher PCR (pellicle cleaning ratio) measure. All toothpastes with the ADA seal of approval have an RDA below 250 and are therefore recognized as containing sufficiently gentle abrasive systems for cleaning without undue harm to hard tissues. The ADA does not acknowledge different classes of toothpastes as being more or less safe for use based on their relative RDA values. As long as they meet the standard of ≤ 250 they are considered equally safe for long-term daily use.

category.¹⁴¹ Crest HD has a two-step system to ensure stability of the 3% hydrogen peroxide for maximum effectiveness.¹⁴²

A second chemical mechanism can be found with agents like **polyphosphates** for both lifting and removing existing stain and also preventing new stain uptake and adherence to the tooth surface by displacing stain molecules from binding sites on the tooth surface and the pellicle. An example of this ingredient is sodium hexametaphosphate (also a tartar control agent) and is found in some marketed whitening dentifrices.¹⁴³

Two ingredients with a shorter history and more limited usage in toothpastes marketed to whiten teeth than those reviewed previously may be mentioned. Blue covarine is a blue pigment that is applied to the enamel in a dentifrice during toothbrushing, reporting

changing the tooth color – as evaluated by the L*a*b* color system – from yellow to more blue, for an immediate effect in making teeth appear whiter.¹⁴⁴ Activated charcoal, a porous form of carbon, can augment a toothpaste’s abrasive system in fighting surface stains but does not provide a bleaching action. A literature review published in the *Journal of the American Dental Association* concluded that more clinical research establishing charcoal’s whitening effectiveness is needed.¹⁴⁵

Guiding Patients to Make a Great Choice

Evaluating the Claims

This course has walked through considerations in evaluating the considerable differences between, and relative benefits of, marketed toothpastes. To answer the original question from the Introduction, all toothpastes are **not**

interchangeable. Individual oral health needs – both therapeutic and cosmetic – should inform the decision around toothpaste selection.

In review, here are some key considerations when evaluating a toothpaste:

- What are the toothpaste therapeutic benefits I am seeking?
- Does it have the ADA seal?
- Do the ingredients have an established and/or well-studied history? If not, does support for any claims exist?
- What laboratory and clinical research data are available?
- How many and what type of benefits can be expected?
- Will the toothpaste contribute to an enjoyable brushing experience to promote compliance?

Where possible, dentifrice ingredient labels should be reviewed to understand potential effects and benefits. Ideally, product packaging claims can be compared to any existing laboratory and clinical research findings on a toothpaste's safety and effectiveness (visit manufacturer's websites – including any sections directed to professionals – and research databases like PubMed). This is especially helpful for dentifrices with lesser-studied ingredients or those with new indications. Peer-reviewed published randomized controlled clinical trials are the gold standard for products making therapeutic claims. For those with less time to read the original publications, research summaries are often available from manufacturer representatives.

Credentialing via the receipt of the ADA Seal of Acceptance is another excellent assurance of a toothpaste's safety and effectiveness.

Conclusion

Toothpastes have evolved immensely since their earliest forms, when they served primarily as a toothbrush aid to attempt to make the teeth less yellow and freshen the mouth. Beginning with the 1950's public health breakthrough when dentifrices began use as vehicles to deliver fluoride, continual scientific advancement in toothpaste formulation technology has yielded increasingly efficacious products. A broad array of toothpaste types for nearly every indication has made it possible to tailor selection to meet the majority of patients' daily oral hygiene needs.

Patients often look to their dental care providers for guidance on which toothpaste is most appropriate. Nearly all dental professionals would concur that the most important ingredient in a marketed toothpaste is fluoride. For many patients, a multi-benefit toothpaste with bioavailable stannous fluoride will be a wise choice, given that it fights so many common conditions and issues simultaneously (caries, plaque, gingivitis, acid erosion, dentinal hypersensitivity, dental calculus, oral malodor). A product that provides noticeable results and is convenient to use is more likely to encourage compliance. Other patients may elect to use a single-indication dentifrice, or make a choice based on their unique preferences for flavors and brushing sensory experiences.

However, an understanding of the differences between dentifrices goes a long way to ensuring a good match between a patient's unique oral health needs and knowledge of products that will help them to achieve their goals. Future research and development undoubtedly promises to expand even further the usefulness of toothpaste as a delivery system for ingredients that enhance health and quality of life.

Course Test Preview

To receive Continuing Education credit for this course, you must complete the online test. Please go to: www.dentalcare.com/en-us/professional-education/ce-courses/ce565/test

- 1. Dental caries and periodontal disease are the two most common and largely preventable oral health conditions.**
 - A. True
 - B. False
- 2. Which of the following ingredients serves as a surfactant in toothpastes?**
 - A. Sorbitol
 - B. Xanthan
 - C. Sodium lauryl sulfate
 - D. Pyrophosphate
- 3. The etiology of tooth decay involves the interplay between ingested sugars, bacteria in the biofilm, and the integrity of the tooth surface.**
 - A. True
 - B. False
- 4. Fluoride, delivered either through topical professional application or found within a dentifrice, _____.**
 - A. deters demineralization and enhances remineralization
 - B. enhances demineralization and slows remineralization
 - C. replaces hydroxyapatite crystals with fluorapatite crystals
 - D. A and C
- 5. Over the counter fluoride toothpastes should be formulated in the correct fluoride concentration of _____.**
 - A. 500-2000 ppm
 - B. 500-1000 ppm
 - C. 1000-1500 ppm
 - D. 1250-1750 ppm
- 6. Which of the following fluorides are not approved for usage in OTC dentifrices under the US Monograph System?**
 - A. Acidulated phosphate fluoride (APF)
 - B. Sodium fluoride (NaF)
 - C. Sodium monofluorophosphate (MFP)
 - D. Stannous fluoride (SnF₂)
- 7. Which of the following statements is NOT true about gingivitis?**
 - A. Patients who brush daily are at low risk for developing gingivitis.
 - B. Gingivitis prevalence is high worldwide.
 - C. Some individuals are hypersensitive to even small amounts of plaque.
 - D. Adjunctive antimicrobial use via toothpaste can aid in gingivitis prevention.
- 8. Which of the following statements are true about stannous fluoride?**
 - A. Unlike sodium fluoride, it does not require formulation stabilization for bioavailability.
 - B. It is the sole anti-caries agent with concurrent anti-gingivitis and anti-hypersensitivity actions.
 - C. It will always produce extrinsic staining when used in a toothpaste.
 - D. B and C
 - E. A and B

9. **One drawback to the use of stannous fluoride in a dentifrice is its weak substantivity.**
A. True
B. False
10. **Which types of dentifrices can treat dentinal hypersensitivity?**
A. Those containing bioavailable stannous fluoride.
B. Those containing potassium nitrate.
C. OTC dentifrices have not been shown to be efficacious in reducing hypersensitivity.
D. A and B
11. **Consider these statements about dental erosion: It is closely related to dentinal hypersensitivity, because acid exposure to dentin tubules precipitate both. SnF_2 treats it by depositing a protective layer on the enamel pellicle surface.**
A. The first statement is true, but the second statement is false.
B. The first statement is false, but the second statement is true.
C. Both statements are true.
D. Both statements are false.
12. **Which of the following is NOT a clinically proven tartar control ingredient?**
A. Pyrophosphates
B. Sodium Hexametaphosphate
C. Zinc citrate
D. Potassium nitrate
13. **Which of the following strategies has been shown to result in bacterial kill and subsequent clinically demonstrated oral malodor reduction?**
A. Brushing with a bioavailable stannous fluoride dentifrice.
B. Brushing with a potassium nitrate sodium fluoride dentifrice.
C. Using an antimicrobial mouthrinse like cetylpyridinium chloride (CPC).
D. A and B
E. A and C
14. **Which of the following works by whitening and preventing calculus formation?**
A. A polypyrophosphate prevents stain absorption via blocking binding sites.
B. A bleaching agent like hydrogen peroxide disrupts carbon bonds to lighten stains.
C. The abrasive system physically lifts and polishes away surface stains.
D. A and C
15. **The RDA abrasivity limit of ____ for a toothpaste ensures no more than 1mm of dentin wear with regular brushing, and that it is safe for a lifetime of usage.**
A. ≤ 275
B. ≤ 250
C. ≥ 225
D. None of the above.
16. **Receipt of the Seal of Acceptance from the American Dental Association ensures that a toothpaste contains fluoride. The Seal signifies that the dentifrice has met ADA's requirements for demonstrated safety and efficacy.**
A. The first statement is true, but the second statement is false.
B. The first statement is false, but the second statement is true.
C. Both statements are true.
D. Both statements are false.

- 17. The following effects have been clinically demonstrated with use of a bioavailable/stabilized SnF₂ multi-benefit toothpaste:**
- A. Reduction/prevention of gingivitis, plaque, and acid erosion
 - B. Reduction/prevention of dental calculus, dentinal hypersensitivity, oral malodor
 - C. A and B
 - D. Neither A nor B; results have been demonstrated in laboratory testing only.
- 18. Which of the following can be useful to a clinician in aiding a patient with a toothpaste recommendation that best meets their needs?**
- A. Global sales data
 - B. Laboratory and clinical trial findings
 - C. Presence of the ADA Seal of Acceptance
 - D. A and C
 - E. B and C

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Additional Resources

- No Additional Resources Available.



About the Author

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Shelly L. Campbell, RDH, MPH received her BS in Dental Hygiene from the University of Iowa and MPH from St. Louis University. She has worked in private practice, the UMKC School of Dentistry's clinical research center, and for the last three decades in industry and then independent oral health clinical research.

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