

THE DANGERS OF SODA POP

4 CE CREDITS

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Introduction

Enamel is the hardest substance in the body and it protects the crowns of the teeth. But it is susceptible to demineralization from acids. Acids are produced when certain bacteria colonize the tooth surface and metabolize carbohydrates. If this process continues it may eventually lead to the development of carious lesions in the enamel and dentin. Another source of acid is dietary. Many foods and beverages contain acids that also can lead to demineralization of the enamel.

Soda pop has emerged as one of the most significant dietary sources of acid capable of producing demineralization of the enamel. Many brands of soda pop also contain sugars that are fermented by bacteria that produce acid by-products. It also appears that soda pop contains other ingredients that produce demineralization independent of its content of acid content or fermentable sugars¹. The danger of soda pop to demineralization of the enamel and its consequences should not be underestimated.

Soda Pop Consumption

The consumption of soda pop in the United States has increased in alarming proportions. This increase in consumption crosses all demographic boundaries.

has been recognized by a number of professional associations.

Recently the American Academy of Pediatrics published a position paper to inform health care professionals, school personnel and parents about the significant dangers posed by the ever-increasing amounts of soda pop consumed by children and teenagers². Between 56%-85% of school age children consume at least one serving of soda pop each day. Often the amount of soda pop consumed daily is much larger. At least 20% of school age children consume a minimum of four soda pop servings every day³. Some of these trends are summarized in Figure 1.

The potential ravages of soda pop caries in teenagers should not be underestimated. Some teenagers drink as many as 12 cans of soda pop a day. In one well-documented case, a teenager who grew up drinking fluoridated water and brushing twice daily with a fluoride containing toothpaste developed caries in every one of his erupted teeth necessitating two extractions and many restorations. Diet analysis revealed that he daily consumed 6-12 cans of soda pop.⁴ See Figure 2 for an example of erosion. Other case reports have demonstrated similar findings among other adolescents and teenagers where chronic, high soda pop consumption is linked with

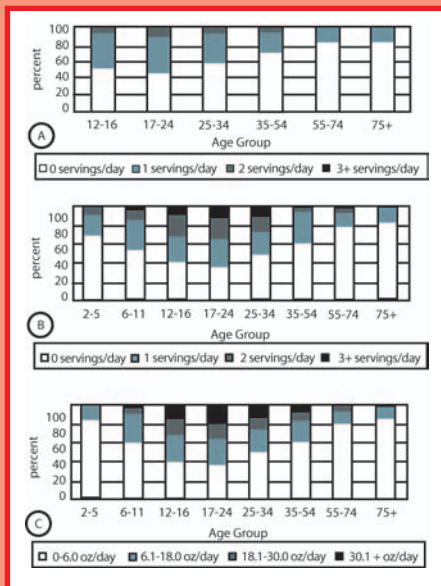


Figure 1. Adapted from Figure 1 in Frequency distribution of sugared soda consumption servings and quantities by age group. Heller K, Burt A, Eklund S. Sugared soda consumption and dental caries in the United States.



Figure 2. Photo by Dr. Peter Endo.

widespread demineralization of enamel and extensive caries in pits and fissures and in the interproximal areas⁵.

Soda Pop in the Schools

One new major development in this problem has been the increased access to soda pop in the schools. Many schools throughout the country have easy access to commercial soda pop vending machines. Students have free and easy access to purchase soda pop at will. The amount of soda pop consumed by students in schools in fact has increased dramatically and continues to increase.

Everybody is drinking more soda pop and drinking it more frequently. This has created a public health crisis, which

Some commercial soda pop vendors provide deep discounts to the schools to allow them to place their vending machines on school premises. In times of budgetary constraint these offers may be difficult to ignore. Student governments may also favor the placement of soda pop dispensing machines in schools.

This has become a controversial issue in some areas. Some parent-teacher organizations have sought to have these soda pop vending machines removed from school premises. This may lead to hotly contested conflicts at meetings on various levels in the school districts. Sometimes the vending machines are removed.

Soda Pop in the Market Place

Soda pop has become a firmly entrenched staple of the American diet and as American as apple pie. The commercial soda pop manufacturers have invested a fortune in advertising and they have created one of the most successful marketing campaigns in American history. Soda pop has become an integral part of American culture.

In the 1950's the typical soda pop serving size was 6.5 oz. By the 1960's this had increased to 12 oz. In the 1990's the typical serving size ballooned up to 20 oz. It is clear that not only are we drinking more soda pop but also we are buying it in ever increasing amounts. This trend is also reflected in fast food outlets, which have been steadily increasing the volume of soda pop in each of their beverage serving sizes.

A Hidden Danger

One of the concomitant problems with the increase in soda pop consumption is that it leads people into drinking less milk, which indirectly leads to a higher incidence of demineralization and caries. Milk contains calcium lactate, which stimulates remineralization of enamel⁶. The regular consumption of adequate quantities of milk bathes the teeth in calcium and calcium lactate and promotes remineralization⁷ to combat the demineralization and erosion caused by soda pop. Thus on the one hand the means for combating enamel erosion is being compromised because people are drinking less milk and on the other hand the increased consumption of soda pop contributes to the more rapid and extensive demineralization of the enamel⁸.

Bacteria Produce Acids that Demineralize Enamel

Dental caries is an infectious, chronic, multifactorial disease⁹. The disease process is initiated when bacteria are passed from the parent to the infant or toddler. These

bacteria later colonize the outer surface of the enamel, form a dental plaque and begin metabolizing carbohydrates like the sugars sucrose and fructose which cause a lowering of the pH of saliva and a consequent demineralization of the enamel. When the pH drops below 5.5 for long periods or repetitively there is a significant chance that this demineralization will lead to the development of carious lesions in the enamel.

Streptococcus mutans is the most significant of the bacteria involved in the development of dental caries. *Lactobacillus* and *Actinomyces viscosus* colonize later and are also important in generating acid by-products.

Enamel experiences continual cycles of demineralization and remineralization. This is a dynamic process that can proceed in either direction. Factors on either side of this equation may change, shifting the reaction in one direction or the other. For many people and in many cases, increasing the sugar content of their diet can increase the demineralization and increase the chance that this may eventually lead to the development of caries.

Soda pop is most commonly sweetened by adding sucrose or high-fructose corn syrup. This yields the equivalent of 10-12 teaspoons of sugar in the typical 12-oz. can of naturally sweetened soda pop. These sugars fuel the metabolism of bacteria that produce the acids, which demineralize enamel. For many people, soda pop is the single biggest source of sugar in their diet. The greater the exposure to these sugars, the more acid produced by the bacteria and the greater the chance of demineralization.

Soda Pop And Acid

In the past the focus of the deleterious effects of soda pop has been on its sugar content and its role in sustaining bacterial growth and acid by-products. However it is clear now that there are two significant threats posed by soda pop. The sugar content certainly does fuel the bacteria that produce acidic by-products, which does have a significant effect on the demineralization of enamel and development of caries. But soda pop also exerts a profound deleterious effect by bathing the teeth in acid that also is capable of producing demineralization.

There is no question that enamel can be demineralized by exposure to soda pop¹⁰. Depending on the kind and brand, soda pop may contain carbonic, phosphoric, malic, citric and tartaric acids and have an acidic pH.¹¹ Some soda pops, which have an acidic pH, are listed in Table 1¹². Repeated exposure to these acids produces demineralization and erosion of the enamel. Demineralization of enamel is inversely related to the pH of the soda pop. The more acidic the soda pop, (i.e., the

lower its pH), the more rapid and profound the demineralization of the enamel¹³.

Table 1. Soda pop with acidic pH

Ginger Ale	2-4
Coca-Cola	2.7
Root beer	3.0
Orange Crush	3.1
Pepsi Cola	3.3
7-Up	3.5

Brands of soda pop that contain artificial sweeteners still pose a significant threat because of their acidic content. While they may not contain sucrose or fructose or other fermentable carbohydrates their acidic content will contribute to the demineralization of enamel. Their threat may not be as great but they are still capable of producing demineralization. In any case these brands of soda pop only account for 14% of the market share¹⁴.

Long-term consumption of soda pop has a significant cumulative effect on the demineralization of enamel¹⁵. The older a person is and the longer that person has been drinking soda pop the more likely that person will have a higher than expected DMFS¹⁶. In people 25 or older there is a statistically significant association between long-term soda pop consumption and higher than expected DMFS. As more people are living longer, more teeth will be experiencing this long-term cumulative exposure to soda pop and we can expect more and more chemical erosion of the enamel with consequent demineralization and dissolution of tooth structure and development of caries.

How Saliva Buffers Acids

One of the body's most effective means for protecting the enamel of the teeth against acid is saliva. Saliva contains many components such as calcium ions, phosphorous ions, proteins, enzymes and bicarbonates. One of its most important functions is to bathe the teeth in a supersaturated solution of calcium and phosphorous so that the enamel of the teeth is constantly exposed to replace any loss of tooth structure due to demineralization. A second function of saliva is to buffer the pH of saliva to prevent the oral environment from becoming too acidic¹⁷. Normal salivary pH is about 6.3. When the pH of saliva drops below 5.5, demineralization usually ensues.

The mechanism for the buffering effect of saliva involves the activity of the bicarbonate ions. As the acid content of saliva increases, the concentration of hydrogen ions increases which lowers the pH. The enzyme carbonic

anhydrase, found in saliva, catalyzes the reaction between the free hydrogen ions from the acid and the bicarbonate ion¹⁸. The end products of this reaction are water and carbon dioxide gas, which is released from the oral cavity as depicted in Figure 3. As more free hydrogen ions combine with bicarbonate ions, the pH begins to rise and the saliva begins to return to normal pH levels¹⁹.

The buffering capacity of saliva varies from person to person. Patients whose saliva has a depressed buffering capacity are more susceptible to erosion from acid²⁰. Salivary flow also determines the capacity of saliva to buffer against acid. The greater the salivary flow the more bicarbonate ions available for combining with free hydrogen ions. When acid is introduced into the oral cavity salivary flow is stimulated and increases within minutes. Normal salivary flow rates are generally between 0.1-0.6 ml per minute²¹. Salivary flow less than 0.1 ml per minute is considered low²².

The chemical reaction between the hydrogen ions released from acids and the bicarbonate ions in saliva protects the enamel from demineralization. Without this protective buffering capacity of saliva, enamel would be demineralized and lost. But this buffering capacity of saliva is limited and can be overwhelmed by frequent or long-term exposure to acids.

The Dangers of Softened Enamel

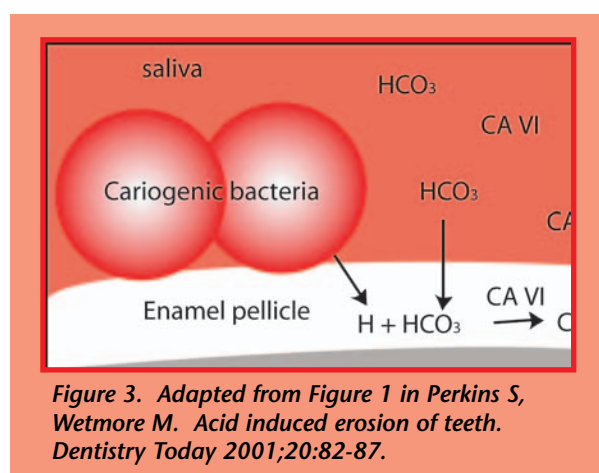


Figure 3. Adapted from Figure 1 in Perkins S, Wetmore M. Acid induced erosion of teeth. Dentistry Today 2001;20:82-87.

When enamel is softened by exposure to soda pop it is in increased danger of being worn away or abraded. This may result in a synergism with other causes of tooth loss such as from vigorous tooth brushing with a hard-bristle toothbrush or from bruxism.

Recognizing the Signs of Soda Pop Erosion

Patients with soda pop erosion present with certain changes in the morphology and surface characteristics of their teeth. Smooth surface enamel may develop broad shiny concavities. The teeth may even have a glazed appearance. Mandibular premolars and molars commonly develop these wide concavities on their buccal surfaces in the cervical third. These may terminate at the free gingival margin producing a characteristic enamel cuff at the free gingival margin or they may extend on to the root surface if the roots are exposed. The occlusal surfaces of premolars and molars may be punctuated by deep shiny concavities that may extend down to dentin. The occlusal surfaces that have been partially restored may



Figure 4 Photo by Dr. Peter Endo.

demonstrate loss of enamel around the occlusal aspect of the restoration so that it appears to rise above the existing occlusal surface. The maxillary central incisors may appear thinner with an increase in incisal translucency. The surface appears polished and smooth and distinctive surface characteristics are missing.

In the primary dentition there is a loss of surface definition and details. The enamel and dentin layers are much thinner than in the permanent dentition and there is an increased chance of erosion leading to pulp exposure. Erosion of the occlusal surface of permanent first molars may result in sealants appearing to rise above the occlusal surface²⁴.

Recognizing Patients at High Risk

Diminished Salivary Flow and Xerostomia

Low salivary flow means less saliva available to rinse soda pop off the teeth and less bicarbonate ions to buffer the acids in soda pop and the acids produced by the fermentation of sugars. Some of the more common signs of low salivary flow include dryness of the lips and buccal mucosa. The dorsum of the tongue may also appear dry and cracked.

The major salivary glands should be palpated and milked. Gentle massaging of the parotid gland should result in the free flow of saliva from Stenson's duct. The submandibular gland should also be gently massaged and saliva should flow freely from Wharton's duct. The saliva should be clear and flow freely.

Low salivary flow can be caused by medical conditions that affect the function of the salivary glands and by certain drug therapies. Some of the more common medical conditions which cause diminished salivary flow include radiation therapy to head and neck and Sjogrens syndrome. Some of the more common drugs that produce diminished salivary flow include alpha blockers and anti-histamines.

Some of these patients with xerostomia or diminished salivary flow may sip soda all day long to combat the sensation of dryness in their mouth. This continuous or repeated exposure to soda pop in the absence of the protective effects of saliva can be devastating.

Recognizing Destructive Habits

Some patients have destructive habits involving the consumption of soda pop. For example some patients derive pleasure from holding soda pop in their mouth and allowing it to bathe certain teeth. Some may actually swish the soda pop around and around for several minutes before swallowing. The carbonation and effervescence of the soda pop produces a pleasure sensation. This can lead to excessive erosion of particular teeth in particular areas²⁵.

Orthodontics

Demineralization and caries have been traditional dangers with cemented brackets in fixed orthodontics. Patients undergoing this mode of therapy must practice meticulous oral hygiene in order to protect their teeth. Increased soda pop consumption poses a significant threat to the development of caries around fixed orthodontic appliances. In one case report a teenager who consumed 2-4 liters of cola soda pop per day presented with significant demineralization around and under fixed cemented brackets. In some cases the demineralization led to a loss of 0.5 millimeters of enamel²⁶. Patients with orthodontic bands have significantly higher prevalence of *Streptococcus mutans*.²⁷

Meticulous oral hygiene and homecare is essential to protect teeth with bands or bonded brackets. The hygienist or dentist may consider the added protection of placing sealant around the margins of the bands or brackets to enhance the sealing effect of the cement.²⁸

Role of Hygienist

The hygienist spends more chair time with the typical dental patient than any other member of the dental team. This affords the hygienist an excellent opportunity to really get to know the patient and to establish rapport. The hygienist is in an excellent position to formulate a realistic risk assessment of the patient.

One of the most effective techniques for identifying patients with a high risk of soda pop is to assess how often and how much is consumed. The patient can be asked how often and how much soda pop they drink. Some patients only drink soda pop at meals, some in-between meals as well and some all day long. Patients may also be able to describe how much soda pop they drink in a day or week. The patient should be asked about the kinds of soda pop they drink. Some soda pops are more acidic than others and some contain more sugar. Some soda pops contain artificial sweeteners and so do not pose a threat from the perspective of bacteria metabolizing sugars.

Home care and oral hygiene should be assessed. The hygienist should ask the patient how many times they brush and which brand of tooth paste they use. The patient should also be asked if they use a fluoride mouth rinses. Many patients will also know if their water source is fluoridated.

Diet Counseling

One of the most important things a hygienist can do is diet counseling. Children and adolescents should be counseled to avoid consuming large amounts of soda pop.²⁹ They should be counseled to drink more alternative beverages that contain less sugar and acid such as water, milk and 100% fruit juice. Their parents should also be informed and counseled and should understand how to stock their refrigerators and to replace fruit drinks with high sugar contents with 100% fruit juices and encourage their children to drink these instead. Parents must become informed and involved and must be proactive in encouraging their children to develop more healthful habits.

Adults should be counseled on the dangers of soda pop consumption and should be encouraged to drink more healthful beverages. Destructive habits such as sipping soda pop all day long at work should be identified and discouraged. The hygienist can also counsel the patient to rinse with water after drinking soda pop to evacuate the oral cavity of any remaining vestiges of soda pop, which might prolong exposure to the enamel.³⁰

Therapies to Increase Fluoride

Increasing the patient's exposure to fluorides is one means of combating the demineralizing effect of soda pop. The topical effects of fluoride exposure on erupted teeth has been well documented.³¹ When patients present for scheduled oral prophylaxis, fluoride should be applied in relatively high doses by the hygienist in the dental office. The hygienist should also counsel the patient to use a fluoride mouth rinses and fluoride toothpaste as part of their regular home care. Repeated exposure to fluoride within safe limits stimulates remineralization and prevents further demineralization and erosion.

Professionally Applied Fluoride

When the patient presents for oral prophylaxis the hygienist should apply fluoride in the form of a foam, gel or rinse. The controlled application of relatively high doses of fluoride on a regular basis is one significant advantage for patients to present for professional oral prophylaxis by a dental hygienist. The traditional means of application involves a fluoride gel in an applicator tray or swabbed on the teeth. Fluoride can also be applied using a foam vehicle that decreases the chance of the patient swallowing excess fluoride. The foam is applied by tray or swabbed on the teeth. Some common gel and foam products are listed in Table 2.

Fluoride Mouth Rinses

Rinsing with a mouthwash containing fluoride reduces the incidence of caries and stimulates remineralization. In fluoride deficient areas rinsing once a week with 0.2% sodium fluoride or daily with 0.05% sodium fluoride both significantly reduced the incidence of caries in children.³² In one school-based preventive dental program, rinsing once a week with 0.2% sodium fluoride resulted in a reduction of 85% in the incidence of caries on proximal surfaces.³³

There are numerous mouth rinses with 0.05% sodium fluoride that can be purchased over the counter that can be recommended to the patient. Patients should be advised to use once daily as a regular part of their home care oral hygiene regimen. For patients with higher risk, the hygienist can request that the dentist write a prescription for a mouth rinse with 0.2% sodium fluoride and instruct the patient to rinse once a week.

Fluoride Toothpastes and Gels

Patients should brush with any of the fluoride containing toothpastes on the market. For patients at higher risk the hygienist can request that the dentist write a prescription for a toothpaste with a higher fluoride

content like PreviDent 5000 Plus (Colgate), which has 5000 ppm fluoride.

Sealants

Sealants may not be a long-term effective barrier to the demineralizing effects of soda pop. In one in vitro study teeth were etched and sealed and then immersed in nine different dark cola soda pops. All teeth showed complete or incomplete loss of sealant and significant demineralization.³⁴

Public Awareness

Numerous articles have appeared in newspapers and magazines informing the public of the dangers of soda pop to teeth and to general health.³⁵ Some articles focus on the dangers of consuming too much soda pop and recommend alternative beverages.³⁶ Some articles describe in detail how soda pop produces demineralization and caries.³⁷ Some articles describe new patterns of caries that are becoming more common with increased and chronic consumption of soda pop.³⁸

A great deal of information about the dangers of soda pop can be accessed on the internet. Many articles on this subject appear in many websites. The abclocalgo website has an article describing the dangers of chronic consumption of Mountain Dew in what it calls 'mountain dew mouth'.³⁹ WebMD also has an excellent article on soda pop and caries.⁴⁰

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Questions

1. What is the hardest substance in the body
 - a. Cortical bone
 - b. Cancellous bone
 - c. Enamel
 - d. Dentin
2. When certain bacteria colonize the surface of teeth they can metabolize carbohydrates to produce
 - a. Proteins
 - b. Acids
 - c. Bases
 - d. Salts
3. Soda pop contains
 - a. Flavoring agents
 - b. Water
 - c. Acids
 - d. All the above
4. The consumption of soda pop in the United States is
 - a. Decreasing
 - b. Leveling off
 - c. Increasing
 - d. Dropping dramatically
5. A teenager may drink as many as how many cans of soda pop a day
 - a. Two
 - b. Six
 - c. Eight
 - d. Twelve
6. At least 20% of school age children drink a minimum of how many soda pop servings a day
 - a. One
 - b. Two
 - c. Three
 - d. Four

7. Among adolescents and teenagers, increased soda pop consumption has been linked with

- a. Increased caries
- b. Increased pit and fissure caries
- c. Increased interproximal caries
- d. All of the above

8. Soda pop vending machines are present in many schools throughout the nation

- a. True
- b. False

9. Public opposition to soda pop vending machines in the schools has resulted in

- a. More soda pop vending machines being installed in the schools
- b. Some soda pop vending machines being removed
- c. First amendment law suits
- d. No results

10. The soda pop marketing campaign can be described as

- a. Unsuccessful
- b. A disaster
- c. One of the most unsuccessful advertising campaigns in history
- d. One of the most successful advertising campaigns in history

11. In the 1950's the typical soda pop serving size was

- a. 6.5 oz.
- b. 12 oz.
- c. 20 oz.
- d. 32 oz.

12. In the 1960's the typical soda pop serving size was

- a. 6.5 oz.
- b. 12 oz.
- c. 20 oz.
- d. 32 oz..

13. In the 1990's the typical soda pop serving size was

- a. 6.5 oz.
- b. 12 oz.
- c. 20 oz.
- d. 32 oz.

14. Milk contains what agent that stimulates remineralization of enamel

- a. Carbonate
- b. Anhydrase
- c. Lipase
- d. Calcium lactate

15. Many patients drink less milk because they drink so much soda pop

- a. True
- b. False

16. Increasing soda pop consumption and decreasing milk consumption can lead to

- a. No changes
- b. Increased remineralization
- c. Increased demineralization
- d. Equilibrium in enamel remineralization and demineralization

17. Dental caries is a disease

- a. True
- b. False

18. Dental caries can be characterized as

- a. Infectious
- b. Chronic
- c. Multifactorial
- d. All of the above

19. When the pH of saliva drops below _____ level there is a significant tendency for demineralization to occur

- a. 4.5
- b. 5.5
- c. 6.0
- d. 7.0

20. The most significant of the bacteria involved in the development of dental caries is

- a. Staphylococcus aureus
- b. Streptococcus mutans
- c. Prevotella intermedium
- d. All of the above

21. Enamel experiences continual cycles of demineralization and remineralization

- a. True
- b. False

22. Soda pop is most commonly sweetened by adding

- a. Sucrose
- b. Fructose
- c. High-fructose corn syrup
- d. All of the above

23. The typical 12-oz can of soda pop may have the equivalent of how many teaspoons of sugar

- a. 6
- b. 8
- c. 10-12
- d. 16

24. The threat of demineralization from soda pop has traditionally been attributed to

- a. Acids produced by bacteria which colonize the tooth surfaces
- b. Bases produced by bacteria which colonize the tooth surfaces
- c. Acids and bases produced by bacteria which colonize the tooth surfaces
- d. None of the above

25. Soda pop contains acids which can

- a. Produce demineralization
- b. Produce remineralization
- c. Produce demineralization and remineralization
- d. None of the above

26. Some of the acids in soda pop are

- a. Carbonic acid
- b. Phosphoric acid
- c. Tartaric acid
- d. All of the above

27. The pH of soda pop may be as low as

- a. 1
- b. 2
- c. 3
- d. 4

28. Soda pop with artificial sweeteners is a threat to enamel demineralization because

- a. It contains sucrose
- b. It contains fructose
- c. It contains corn-syrup
- d. It contains acids

29. Soda pop with artificial sweeteners accounts for what percentage of the market share

- a. 10%
- b. 14%
- c. 20%
- d. 30%

30. Long-term consumption of soda pop appears to have a significant cumulative effect on the demineralization of the enamel

- a. True
- b. False

THE DANGERS OF SODA POP

Name: _____

Title: _____ Specialty: _____

Address: _____ Email: _____

City: _____ State: _____ Zip: _____

Telephone: Home () _____ Office () _____

After Reading Instructions: 1) Complete all information above. 2) Answer sheets may be completed with either a pen or pencil. 3) All questions should have only one answer marked. 4) When test is completed, enclose the completed answer sheet. Successful completion of this course will earn you 4 CEUs.

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Please evaluate this course by responding to the following statements, using a scale of:

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____ Yes ____ No
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Any additional comments or criticisms: _____

Check this box to receive score with certificate.

1.	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D	<input type="radio"/> E	16.	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D	<input type="radio"/> E
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Author(s)

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 Michael Florman, DDS
 Sanford A. Aaronson, DDS, MS, JD

EDUCATIONAL OBJECTIVES

This continuing dental education course has been written to review the dangers of soda pop consumption and its effect on oral health.

INSTRUCTIONS

All questions should have only one answer. Grading of this examination is done manually. Participants will receive confirmation of passing by receipt of a certificate. Certificates will be mailed within two weeks after taking and examination.

SPONSOR/PROVIDER

The Academy of Dental Therapeutics and Stomatology, Inc. (ADTS) is the only sponsor/provider. This course was made possible through an unrestricted educational grant from Colgate. No manufacturer or third party has had any input into the development of course content. All content has been derived from references listed, and the opinions of clinicians. Please direct all questions pertaining to the ADTS or the administration of this course to the current director, Michael Florman, D.D.S.: P. O. Box 116, Chesterland, OH 44026 or florman@ineedce.com

COURSE CREDITS/COST

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REFUND POLICY

Any participant who is not 100% satisfied with this course can request a full refund by contacting the Academy of Dental Therapeutics and Stomatology in writing.

COURSE EVALUATION

We encourage participant feedback pertaining to all courses. Please be sure to complete the attached survey included with the answer sheet.

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Rx only

DESCRIPTION: Self-topical dental fluoride dentifrice containing 1.1% (w/w) sodium fluoride for use as a dental caries preventive in adults and pediatric patients.

Active Ingredient: Sodium fluoride (NF) 1.1% (w/w).

Other Ingredients: Spearmint flavor, purified water, sorbitol, hydrated silica, H3G-12, sodium lauryl sulfate, sodium phosphate monobasic, fluor, xanthan gum, tetrapotassium pyrophosphate, sodium benzoate, sodium saccharin, mica, FD&C Blue #1.

Fluoristic™ flavor: sorbitol, purified water, hydrated silica, H3G-12, sodium lauryl sulfate, sodium phosphate monobasic, xanthan gum, tetrapotassium pyrophosphate, sodium benzoate, fluor, sodium saccharin, mica, D&C Red #33.

CLINICAL PHARMACOLOGY: Frequent topical applications to the teeth with preparations having a relatively high fluoride content increase tooth resistance to acid dissolution and enhance penetration of the fluoride ion into tooth enamel.

INDICATIONS AND USAGE: A dental caries preventive for one daily self-applied topical use. It is well established that 1.1% sodium fluoride is safe and extraordinarily effective as a caries preventive when applied frequently with multiple applications.^{1,4} PreviDent® 5000 Booster brand of 1.1% sodium fluoride in a squeeze bottle is easily applied onto a toothbrush. This prescription toothpaste should be used once daily in place of your regular toothpaste unless otherwise instructed by your dental professional. May be used in areas where drinking water is fluoridated since topical fluoride cannot produce fluorosis. (See **WARNINGS** for exception.)

CONTRAINDICATIONS: Do not use in patients with dysphagia. Do not use in pediatric patients under age 6 years unless recommended by a dentist or physician.

WARNINGS: Prolonged daily ingestion may result in various degrees of dental fluorosis in pediatric patients under age 6 years, especially if the water fluoridation exceeds 0.6 ppm, since younger pediatric patients frequently cannot perform the brushing process without significant swallowing. Use in pediatric patients under age 6 years requires special supervision to prevent repeated swallowing of toothpaste which could cause dental fluorosis. Pediatric patients under age 12 should be supervised in the use of this product. Read directions carefully before using. Keep out of reach of infants and children.

PRECAUTIONS:

General: Not for systemic treatment. **DO NOT SWALLOW.**

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a study conducted in rodents, no carcinogenesis was found in male and female mice and female rats treated with fluoride at dose levels ranging from 4.1 to 9.1 mg/kg of body weight. Equivocal evidence of carcinogenesis was reported in male rats treated with 2.5 and 4.1 mg/kg of body weight. In a second study, no carcinogenesis was observed in rats, males or females, treated with fluoride up to 11.3 mg/kg of body weight. Epidemiological data provide no credible evidence for an association between fluoride, either naturally occurring or added to drinking water, and risk of human cancer. Fluoride ion is not mutagenic in standard bacterial systems. It has been shown that fluoride ion has potential to induce chromosome aberrations in cultured human and rodent cells at doses much higher than those to which humans are exposed. *In vivo* data are conflicting. Some studies report chromosome damage in rodents, while other studies using similar protocols report negative results. Potential adverse reproductive effects of fluoride exposure in humans has not been adequately evaluated. Adverse effects on reproduction were reported for rats, mice, fox, and cattle exposed to 100 ppm or greater concentrations of fluoride in their diet or drinking water. Other studies conducted in rats demonstrated that lower concentrations of fluoride (5 mg/kg of body weight) did not result in impaired fertility and reproductive capabilities. **Pregnancy: Teratogenic Effects: Pregnancy Category B.** It has been shown that fluoride crosses the placenta of rats, but only 0.03% of the amount administered is incorporated in fetal tissue. Animal studies (rats, mice, rabbits) have shown that fluoride is not a teratogen. Maternal exposure to 12.2 mg fluoride/kg of body weight (rats) or 13.1 mg/kg of body weight (rabbits) did not affect the litter size or fetal weight and did not increase the frequency of skeletal or visceral malformations. There are no adequate and well-controlled studies in pregnant women. However, epidemiological studies conducted in areas with high levels of naturally fluoridated water showed no increase in birth defects. Heavy exposure to fluoride during *in utero* development may result in skeletal fluorosis which becomes evident in childhood.

Nursing Mothers: It is not known if fluoride is excreted in human milk. However, many drugs are excreted in milk, and caution should be exercised when products containing fluoride are administered to a nursing woman. Reduced milk production was reported in farm-raised fox when the animals were fed a diet containing a high concentration of fluoride (8-137 mg/kg of body weight). No adverse effects on parturition, lactation, or offspring were seen in rats administered fluoride up to 5 mg/kg of body weight.

Pediatric Use: The use of PreviDent® 5000 Booster in pediatric age groups 6 to 16 years as a caries preventive is supported by pioneering clinical studies with 1.1% sodium fluoride gels in mouth trays in students age 11 to 14 years conducted by Englander et al.^{2,5} Safety and effectiveness in pediatric patients below the age of 6 years have not been established. Please refer to the **CONTRAINDICATIONS** and **WARNINGS** sections.

Geriatric Use: Of the total number of subjects in clinical studies of 1.1% (w/w) sodium fluoride, 15 percent were 65 and over, while 1 percent were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.⁵

ADVERSE REACTIONS: Allergic reactions and other idiosyncrasies have been rarely reported.

OVERDOSAGE: Accidental ingestion of large amounts of fluoride may result in acute burning in the mouth and sore tongue, nausea, vomiting, and diarrhea may occur soon after ingestion (within 30 minutes) and are accompanied by salivation, hematemesis, and epigastric cramping abdominal pain. These symptoms may persist for 24 hours. If less than 5 mg fluoride/kg body weight (i.e., less than 2.3 mg fluoride/lb body weight) have been ingested, give calcium (e.g., milk) orally to relieve gastrointestinal symptoms and desolve for a few hours. If more than 5 mg fluoride/kg body weight (i.e., more than 2.3 mg fluoride/lb body weight) have been ingested, induce vomiting, give orally soluble calcium (e.g., milk, 5% calcium gluconate or calcium lactate solution) and immediately seek medical assistance. For accidental ingestion of more than 15 mg fluoride/kg of body weight (i.e., more than 6.9 mg fluoride/lb body weight), induce vomiting and admit immediately to a hospital facility.

A treatment dose (a thin ribbon) of PreviDent® 5000 Booster contains approximately 2.5 mg fluoride. A 3.58 fl. oz. (106 mL) bottle of PreviDent® 5000 Booster contains approximately 647 mg fluoride.

DOSE AND ADMINISTRATION: Follow these instructions unless otherwise instructed by your dental professional. 1. Adults and pediatric patients 6 years of age or older, apply a thin ribbon of PreviDent® 5000 Booster to a toothbrush. Brush thoroughly once daily for two minutes, preferably at bedtime, in place of your regular toothpaste. 2. After use, adults expectorate. For best results, do not eat, drink, or rinse for 30 minutes. Pediatric patients, age 6-16, expectorate after use and rinse mouth thoroughly.

HOW SUPPLIED:

3.58 fl. oz. (106 mL) in plastic bottles

Spearmint: NDC 0126-0075-34

Fluoristic™: NDC 0126-0076-34

STORAGE: Store at Controlled Room Temperature, 20-25 °C (68-77 °F).

REFERENCES: 1. American Dental Association, Accepted Dental Therapeutics B3, 40 (Chicago, 1994): 405-407. 2. H.R. Englander et al., JADA 75 (1967): 638-644. 3. H.R. Englander et al., JADA 78 (1969): 783-787. 4. H.R. Englander et al., JADA 83 (1971): 354-358. 5. Data on file, Colgate Oral Pharmaceuticals.

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US Patent No. 6,280,933
R07817 Rev. 07/03

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References: 1. Joziak MT, et al. Comparison of enamel fluoride uptake and fluoride release from liquid and paste dentifrices. *J Dent Res.* 2003;82(Sp. Issue). Abstract 1355. 2. US Patent 6,290,933. Please see full Prescribing Information on the following page.

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