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(54) METHOD FOR MEASURABLY IMPROVING ORAL HEALTH

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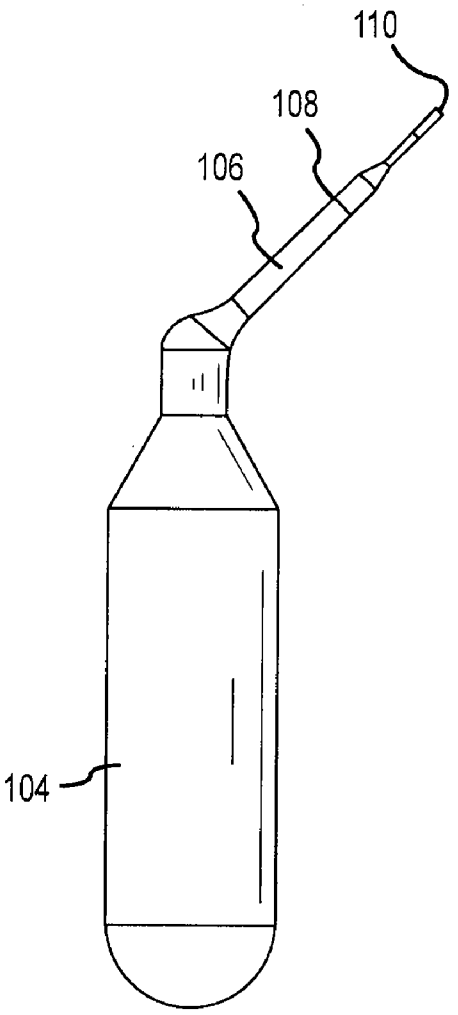
(57) **ABSTRACT**

The present invention provides a method to measurably improve oral health. The method includes use of a composition, including one or more active ingredients to measurably improve oral health, a system including the composition and a container encapsulating the composition, and a kit including a plurality of systems. Each system is configured to apply the composition directly to a surface.



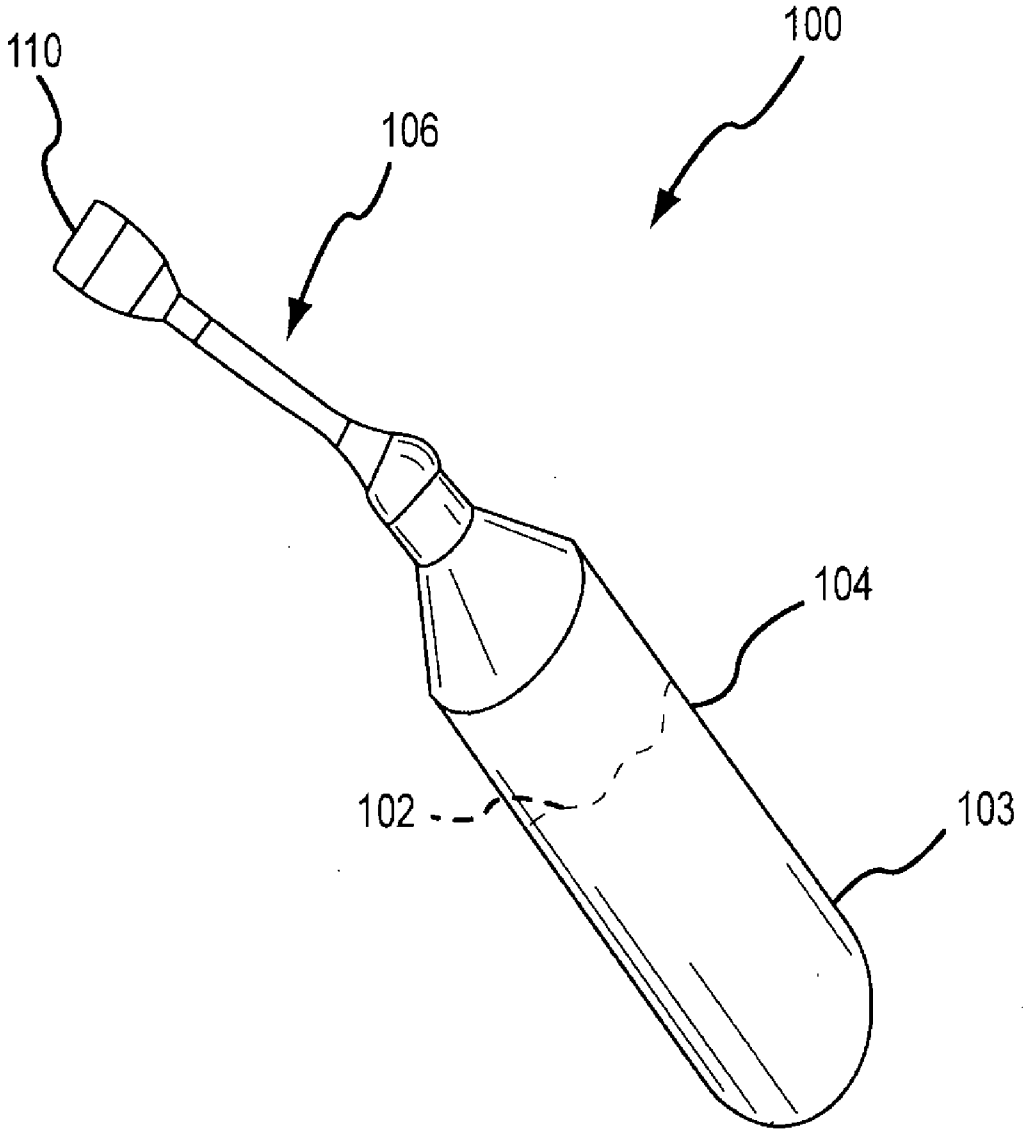


FIG.1

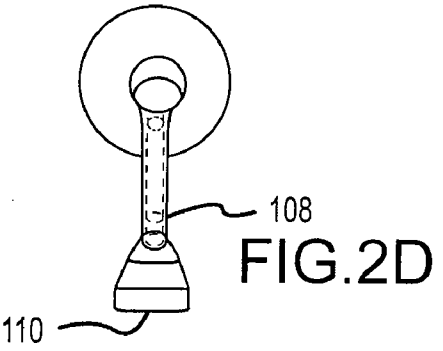


FIG.2D

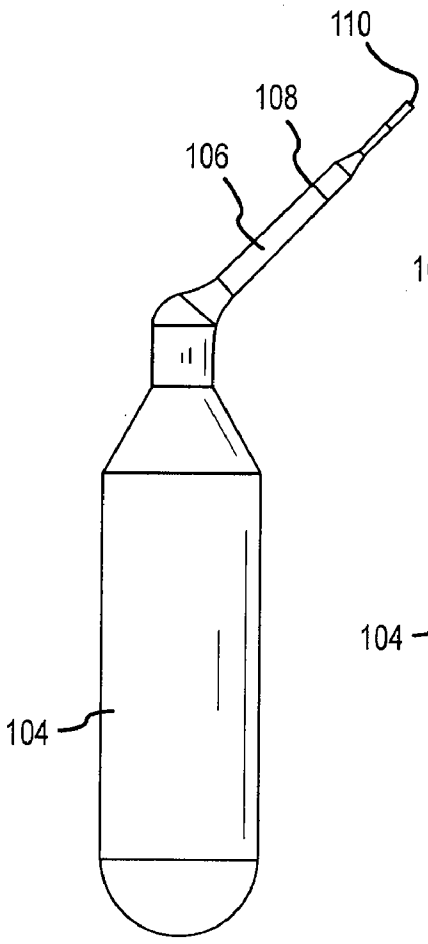


FIG.2A

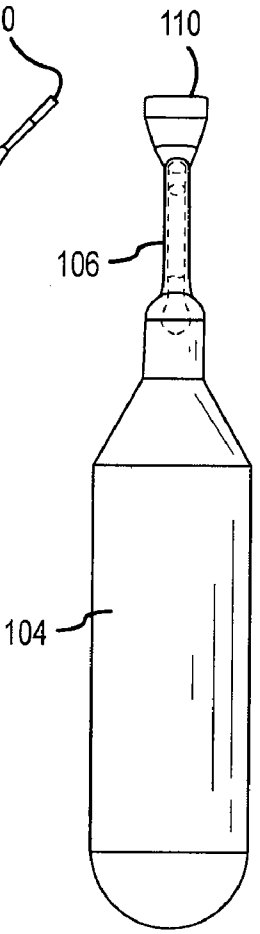


FIG.2B

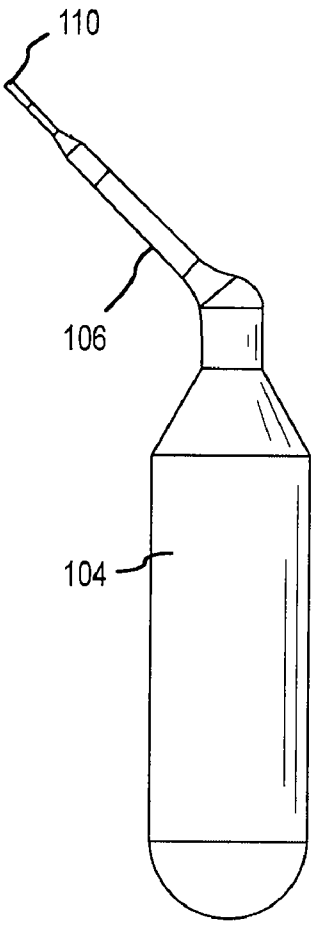


FIG.2C

METHOD FOR MEASURABLY IMPROVING ORAL HEALTH

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application Ser. No. 60/800,632, entitled SYSTEM FOR MEASURABLY IMPROVING ORAL HEALTH AND METHOD OF USING SAME, filed May 15, 2006.

FIELD OF INVENTION

[0002] The present invention generally relates to methods for measurably improving oral health. More particularly, the invention relates to techniques for measurably reducing an amount of plaque, tartar, gingivitis, periodontitis, and/or bleeding of the gums

BACKGROUND OF THE INVENTION

[0003] Unfortunately, poor oral health affects millions of people every year. Poor oral health may result in symptoms ranging bad breath, tooth decay, and tooth discoloration, to more serious health problems, such as gum disease, tooth loss, heart disease, stroke, poorly controlled diabetes and preterm labor.

[0004] The presence of dental plaque, or simply plaque, in an oral cavity can lead to such oral and general health problems. Plaque can be defined as an organized, coherent, gel-like or mucoid material that includes microorganisms in an organic matrix derived from saliva and extracellular bacterial products such as glucans, fructans, enzymes, toxins, and acids. Plaque may also contain other cells, such as desquamated epithelial cells, and inorganic components, such as calcium and phosphate. In general, dental plaque is a bacterial accumulation. Generally transparent and sticky, plaque accumulates around the teeth at the cervical margin, and then grows apically.

[0005] Once plaque forms on a surface, the plaque resists removal, and usually can be removed only by mechanical means, such as, for example, by brushing and flossing the affected areas. If not removed, however, the presence of plaque can give rise to tartar formation, tooth decay, gingivitis, periodontitis, and other health problems.

[0006] Tartar is a hard, calcified plaque material that exhibits a yellowish or brownish color. Tartar forms as a result of minerals (e.g., those present in saliva and gum pockets) reacting with plaque material to form a rough calculus. Calculus generally arises from the nucleation of calcium phosphate, often in areas where the large salivary gland ducts secrete their saliva. As such, calculus can form on surfaces not covered by the oral mucosa (supragingival) or on surface located apical to the soft tissue margin of the gingiva (subgingival).

[0007] Tartar adheres to hard surfaces such as enamel, roots, and dental devices, such as dentures, bridges, crowns, and the like, and is generally more difficult to remove than plaque. Brushing and flossing are normally not sufficient to remove tartar from a surface.

[0008] If left untreated, tartar buildup can be problematic in several regards. For example, the rough, porous surface of tartar serves as a breeding ground for additional bacteria, which can calcify and form additional tartar. The bacteria growth from both plaque and tartar can, in turn, lead to tooth decay, gum disease, gingivitis, periodontitis, tooth loss, as well as systemic health problems.

[0009] Gingivitis is the beginning stage of periodontitis and is often caused by long-term effects of plaque and tartar buildup. Gingivitis is characterized by red, swollen gums. A periodontal probe will often measure about 3 to about 5 mm in depth into the space between the teeth and gums at the early stages of gingivitis. At this stage, gingivitis can often be reversed with proper treatment.

[0010] Left untreated, gingivitis will likely progress to advanced periodontitis. At this stage of gum disease, plaque and tartar are typically present supragingival and subgingival and an infection has destroyed bone around a tooth. In general, at this stage, a family of chronic inflammatory infections are affecting the supporting tissues of the dentition. Teeth often become loose, and the pocket depth may range between about 5 mm and about 8 mm at this stage.

[0011] As noted above, in addition to the health concerns, plaque and tartar may give rise to cosmetic problems. Tartar can be particularly problematic because it is difficult to remove and because of its yellowish or brownish color. Moreover, because the surface of tartar is rough and porous, tartar tends to absorb colors from other sources (e.g., coffee, tea, tobacco, smoke, red wine and the like), and thus the presence of tartar exacerbates cosmetic tooth coloration typically associated with such other sources.

[0012] Typical self-administered techniques for promoting oral health include brushing, flossing, and rinsing with a mouth rinse that typically includes an antimicrobial agent. Although such techniques may work relatively well at mitigating plaque buildup, such techniques are not thought to be effective at removing existing tartar from a surface. Furthermore, although flossing is thought to reduce plaque buildup, relatively few people in the general population floss as often as they should (at least once a day). In a recent study, only 27% of consumers said they flossed once a day.

[0013] The usual methods of preventing tartar buildup include brushing with a tartar control toothpaste. Although such toothpastes, if used regularly, may prevent additional buildup of tartar, the toothpastes are not thought to be effective at removing existing tartar from tooth and device surfaces.

[0014] Typical methods of removing existing tartar typically include scaling or root planing, both of which are performed by dentists or hygienists with the aid of specialized tools. Although these techniques work well, they are relatively expensive and time consuming.

[0015] Accordingly, improved techniques for measurably reducing an amount of tartar, plaque, gingivitis, gum bleeding, periodontitis, and the like are desired.

SUMMARY OF THE INVENTION

[0016] The present invention provides a method for measurably improving oral health. More particularly, the invention provides techniques for using a composition, system, and kit. The composition includes one or more active ingredients to measurably reduce an amount of plaque,

tartar, gingivitis, including gum bleeding, and/or other periodontal disease, a system includes the composition and a container, and a kit includes a plurality of systems.

[0017] While the ways in which the invention addresses the various drawbacks of known methods will be described in more detail below, in general, the present invention provides a relatively inexpensive, safe technique for the measurable improvement of oral care indices, such as Loe and Silness Gingival Index (1963) (GI), the Turesky Modification (1970) of the Quiqley and Hein Plaque Index (PI), Volpe-Manhold Index for Calculus (1965) (V-MI). The method is relatively easy to use, does not require a visit to a dentist office, and does not damage the surface of tooth enamel.

[0018] In accordance with various embodiments of the invention, a method for measurably improving oral health includes use of a system that includes a composition, having one or more active ingredients to measurably improve oral health, and a container for enclosing and applying the composition.

[0019] In accordance with one embodiment of the invention, a system includes a viscous composition including at least one active ingredient and a container configured to dispense the viscous composition. In accordance with various aspects of this embodiment, the viscous composition is designed to maintain the active ingredient(s) in contact with a surface for an extended period of time. Exemplary compositions have a viscosity greater than about 20,000 cp, preferably greater than about 30,000 cp, and more preferably greater than about 35,000 cp. The viscosity of the compositions may range from about 20,000 to about 250,000 cp, preferably about 25,000 to about 100,000, and more preferably about 30,000 to about 50,000 cp. Suitable active ingredients include cetylpyridinium chloride (CPC), zinc salts, other antimicrobial agents, and other ingredients known to improve (typically reduce) measurable oral health care indices. In accordance with additional aspects of this embodiment, the container encapsulates a single dose of the composition, and the system includes a plurality of containers and doses. In accordance with yet further aspects, the container is configured to facilitate application of the composition to specific areas within an oral cavity. In accordance with yet additional aspects of this embodiment, the system is designed to improve one or more oral health indices selected from the group of GI, PI, and V-MI.

[0020] In accordance with another embodiment of the invention, a system includes a composition, having a plurality of active ingredients to measurably improve oral health, and a container to hold the composition. In accordance with various aspects of this embodiment of the invention, the composition includes a carrier having a thickening agent, wherein the composition is configured to maintain the plurality of active ingredients in contact with a surface for an extended period of time. Exemplary thickening agents suitable for use in the composition include hydroxyethylcellulose, and other pharmaceutically acceptable thickeners, and exemplary active ingredients include CPC, zinc salts, other antimicrobial agents, and similar agents known to reduce tartar or plaque or gingivitis. In accordance with additional aspects of this embodiment, the container encapsulates a single dose of the composition, and the system includes a plurality of containers and doses. In accordance with yet further aspects, the container is configured to facilitate application of the composition to specific areas within an oral cavity. In accordance with yet additional aspects of this embodiment, the system is designed to improve one or more oral health indices selected from the group of GI, PI, and V-MI.

[0021] In accordance with a further embodiment of the invention, a system includes a composition, having one or more active ingredients to measurably improve oral health and a carrier including a thickening agent, and a container to hold the composition. Exemplary thickening agents suitable for use in the composition include hydroxyethylcellulose, glycerin, and other pharmaceutically acceptable thickeners, and exemplary active ingredients include CPC, zinc salts, other antimicrobial agents, and similar agents known to improve oral health.

[0022] In accordance with additional embodiments, a system includes a container that encapsulates a single dose of the composition. In accordance with alternative embodiments, the container encloses multiple doses.

[0023] In accordance with various additional embodiments, the composition, system, and kit are designed to improve one or more oral health indices selected from the group of GI, PI, and V-MI.

[0024] In accordance with various additional embodiments, a method includes dispensing a composition from a sealed container by rupturing the sealed container and applying a single dose of the composition directly to the surface. In accordance with another example, the composition is applied after brushing, flossing, and/or rinsing, and is applied before extended rest or bedtime to allow the active ingredients to stay in contact with a surface for an extended period of time

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The exemplary embodiments of the present invention will be described in connection with the appended drawing figures in which like numerals denote like elements and:

[0026] FIG. **1** illustrates a perspective view of a dispensing device in accordance with exemplary embodiments of the invention; and

[0027] FIGS. **2**A-**2**D illustrate, respectively, left view, front view, right view and a top view of an exemplary container in accordance with an exemplary embodiment of the invention.

DETAILED DESCRIPTION

[0028] The present invention provides a method to measurably improve oral health. More particularly, the invention provides a method for using a composition, system, and kit to measurably improve one or more oral health care indices such as GI, PI, and V-MI. The method of the invention can be used to improve oral health of various animals, is particularly well suited for the treatment of humans.

[0029] As used throughout this application, the term "surface" includes any surface on which plaque, tartar, or gum disease may form. Exemplary surfaces include teeth (both supragingival and subgingival), gums, and dental appliances such as bridges, crowns, fillings, braces, and the like.

Further, the term "measurably improve" means a measurable difference between an amount measured without use of the system of the present invention and with or after use of the system. The measurements may be compared for the same surface (before and after) or between test and control groups.

[0030] Viscous Composition

[0031] In accordance with exemplary embodiments of the invention, a method for measurably improving oral health includes a use of a viscous composition, including an active ingredient. As explained in greater detail below, the composition is designed to maintain the active ingredient in contact with a surface for an extended period of time to allow the active ingredient(s) to stay in contact with possibly affected areas on the surface.

[0032] Exemplary active ingredients suitable for use with systems of the invention include one or more of the following: cetylpyridinium chloride (CPC), dicalcium phosphate dehydrate, hydrogen peroxide, sanguinaria extract, sodium bicarbonate, sodium lauryl sulfate, sodium fluoride, stannous fluoride, sodium monofluorophosphate (MFP), zinc salts such as zinc chloride, zinc acetate, zinc citrate, zinc oxide and zinc gluconate, alkyl dimethyl amine oxide, alkyl dimethyl glycine, eucalyptol, menthol, methyl salicylate, thymol, sodium citrate, peppermint oil, sage oil, polymethylsiloxane, polxamer, and stannous pyrophosphate. Other now known or hereafter devised actives may also be used. For example, any agent, which alone or in combination is able to prevent or alleviate the severity of problems associated with dentition may be utilized. Such may include anti-caries agents and the like; agents useful in reducing tooth hypersensitivity, such as potassium nitrate, strontium chloride and/or the like; and/or plaque and calculus reducing agents, such as, for example, chlorhexidine, quaternary ammonium compounds (e.g. benzethonium chloride, domphen bromide, etc.), triclosan, herbal compounds (e.g. sanguinarine), stannous salts, complex phosphates (e.g., pyrophosphates), SLS (e.g. sodium lauryl sulfate), hydrogen peroxide, and/or the like.

[0033] An amount of the active ingredient for use within compositions suitable for uses with the invention varies in accordance with the dosage size and particular ingredient(s). In general, each active or actives selected will be used in a suitably effective amount, generally on the order of less than about 10 wt %, and more preferably 5 wt % or less. An amount of active may also be desirably selected to be within government guidelines, such as guidelines by the Food and Drug Administration in the USA. In particularly preferred compositions, the active ingredient is present in an amount of about 0.001 wt % to about 1.5 wt %, within an amount of about 0.025 wt % to about 1.0 wt %, or even within an amount about 0.05 wt % to about 0.7 wt %. All percentages set forth herein are in weight percent of the total composition, unless otherwise indicated.

[0034] In accordance with particular examples of this exemplary embodiment of the invention, the active ingredient includes CPC. In one case, the CPC is present in an amount of about 0.001% to about 1%, preferably about 0.01% to about 0.5%, and more preferably about 0.05% to about 0.25% or about 0.045% to about 0.1%.

[0035] In accordance with other examples, the active ingredient includes zinc gluconate. In one case, the zinc gluconate is present in an amount of about 0.001% to about 1.5%, preferably about 0.01% to about 1.0%, and more preferably about 0.05% to about 0.75%.

[0036] In accordance with further aspects, the composition includes a thickener to obtain the desired viscosity. Suitable thickening agents include substances which increase the viscosity of the composition, cause the composition to gel or coagulate, or the like, such as food-grade or pharmaceutical grade thickeners, including, for example, hydroxyethylcellulose. For example, hydroxyethylcellulose, hydroxypropyl methylcellulose, carrageenan, guar gum, methylcellulose, methyethylecellulose, acceptable non-ionic thickeners, and/or the like. The thickener may be present in an amount of about 0.01 to about 10%, preferably about 0.1 to about 7%, and more preferably about 1% to about 5%.

[0037] The composition may also include a humectant such a glycerin, which may be present in an amount of about 0.01% to about 15%, preferably about 0.1% to about 10%, and more preferably about 1 to about 7%. When used, the humectant may facilitate maintaining the composition in a liquid form and may help maintain a desired viscosity of the composition. In addition, glycerin may facilitate maintaining one or more of the active ingredients in an ionic form and may facilitate the transport of the active ingredients through the composition.

[0038] The composition may also include a suitable diluent. Exemplary diluents for use with the present composition include water, alcohols, and oils. In accordance with particular examples of the invention, the composition includes purified water in an amount of about 80% to about 99%, preferably about 85% to about 95%, and more preferably about 88% to about 92%.

[0039] The composition may also include sugar alcohols such as sorbitol that act as a sweetener and also as a humectant and/or emulsifier. When used, sorbitol or other sugar alcohol is present in an amount of about 0.001% to about 0.5%, preferably about 0.01% to about 0.1%, and more preferably about 0.025% to about 0.075%.

[0040] The composition may also include a natural or artificial sweetener such as sucralose, ace-K, sodium, saccharin, aspartame, and/or the like, which, when included in the composition, is present in an amount of about 0.001% to about 1.5%, preferably about 0.01% to about 1%, and more preferably about 0.25% to about 0.75%.

[0041] Colorants may also be added to the composition as desired. In accordance with various aspects, the composition includes colorants, such that when the composition is applied to or proximate the gingiva, the composition has a color indicative of healthy gingiva—i.e., the composition is pink in color. Providing a composition having a color indicative of healthy gingiva provides added incentive to users to continue using the composition, which in turn promotes measurable improvement in oral health indices.

[0042] Colorants may be present in any desired amount. By way of particular example, the colorants may include Red #33 and Red #40, available from Pylam in an amount of about 0.000001% to about 0.00018%, and more preferably about 0.00050% to about 0.00099.

[0043] The composition also optionally includes flavorants such as cinnamon oil, clove oil, mint flavorings,

citrus flavorings, and the like. By way of one particular example, a composition includes cinnamon oil present in an about of about 0.001% to about 2%, preferably about 0.01% to about 1%, and more preferably about 0.1% to about 0.5%; and clove oil in an amount of about 0.001% to about 2%, preferably about 0.002% to about 1%, and more preferably about 0.003% to about 0.0075%.

[0044] Preferably, the composition is configured to maintain the composition in contact with a surface for an extended period of time, which has several advantages over traditional compositions used to promote oral health. In this regard, preferably the composition is both viscous and exhibits high micro adhesiveness. In accordance with one preferred embodiment, advantageously the composition is both viscous and "sticks" to a surface to which it is applied. In accordance with one aspect of a particularly preferred embodiment of the present invention, the configuration of the composition permits relatively small amounts of the composition and consequently the active agent(s) to be used to effectively prevent or remove plaque and/or tartar buildup on a surface. This is advantageous, not only from an economic viewpoint, but it also reduces an amount of the composition that may be ingested.

[0045] In general, the viscosity of the composition is suitably selected to facilitate easy delivery of the composition from its container, while also maintaining the composition in contact at particular areas within an oral cavity, such as the crevices within teeth and at the tooth gingival margin. In accordance with further embodiments of the invention, the viscosity is low enough to allow application of the composition to desired locations within the oral cavity.

[0046] Exemplary compositions have a viscosity greater than about 20,000 cp, preferably greater than about 30,000 cp, and more preferably greater than about 35,000 cp. By way of more particular examples, the viscosity of compositions range from about 20,000 to about 250,000 cp, preferably about 25,000 to about 100,000, and more preferably about 30,000 to about 50,000 cp, and yet more preferably about 35,000 to about 45,000 cp. The viscosity values as set forth herein are measured using a Brookfield, Model DV-II+ Pro viscometer, spindle # 6, 10 RPM for 90 seconds at 25 C.

[0047] Active Plus Thickener

[0048] In accordance with another embodiment of the invention, a composition includes one or more active ingredients in a carrier, which includes a thickening agent. The active ingredient and thickening agent may include any one or more of the active ingredients and thickening agents noted above in the respective weight percents noted above. The composition may also include any of the optional ingredients such as sweeteners, flavorants, and colorants as set forth herein.

[0049] By way of example, a composition in accordance with this embodiment of the invention includes CPC and zinc gluconate as the active ingredients and hydroxyethylcellulose as the thickener. In this case, the CPC is present in an amount of about 0.001% to about 1%, preferably about 0.01% to about 0.5%, and more preferably about 0.05% to about 0.25% or about 0.045% to about 0.1%; the zinc gluconate is present in an amount of about 0.001% to about 1.5%, preferably about 0.01% to about 1.0%, and more preferably about 0.05% to about 0.75%; and the hydroxyethylcellulose is present in an amount of an amount of about 0.01 to about 10%, preferably about 0.1 to about 7%, and more preferably about 1% to about 5%.

[0050] Multiple Active Ingredients

[0051] In accordance with another embodiment of the invention, a composition includes multiple active ingredients. The plurality of active ingredients may include any combination of the active ingredients noted above in the weight percents noted above. The composition may also include any of the optional ingredients such as sweeteners, flavorants, and colorants as set forth herein.

[0052] In accordance with one aspect of this embodiment, the composition has a viscosity greater than about 20,000 cp, preferably greater than about 30,000 cp, and more preferably greater than about 35,000 cp. By way of more particular examples, the viscosity of compositions ranges from about 20,000 to about 250,000 cp, preferably about 25,000 to about 100,000, and more preferably about 30,000 to about 50,000 cp, and yet more preferably about 35,000 to about 45,000 cp. In accordance with another embodiment, the composition includes a thickening agent, which is present in an amount of an amount of about 0.01 to about 10%, preferably about 0.1 to about 7%, and more preferably about 1% to about 5%.

[0053] By way of one particular example, a composition in accordance with this embodiment of the invention includes CPC and zinc gluconate as the active ingredients. In one case, the CPC is present in an amount of about 0.001% to about 1%, preferably about 0.01% to about 0.5%, and more preferably about 0.05% to about 0.25%; and the zinc gluconate is present in an amount of about 0.001% to about 1.5%, preferably about 0.01% to about 1.0%, and more preferably about 0.05% to about 0.75%.

[0054] Active Ingredient and Colorant

[0055] In accordance with this embodiment of the invention, a composition includes one or more active ingredients and a colorant indicative of healthy gingiva. In this case, the color of the composition is more than merely decorative. It serves the function of encouraging those that use the product to continue to use the product because there is an immediate appearance, upon application of the composition, that the composition is promoting healthy gingiva.

[0056] System

[0057] FIG. **1** and FIGS. **2**A-**2**D illustrate an enclosed, single-dose dispensing system **100** suitable for applying a composition **102** (e.g. a composition described herein) to a surface. System **100** includes a resilient containment portion **104** and an applicator portion **106**. Applicator portion **106** further includes a severed or scarred area **108** and a sealed end **110**.

[0058] Composition **102** is dispensed from system **100** by severing or rupturing a portion of device **100** (e.g., at or near scarred area **108**) to expose composition **102** contained within system **100**. Composition **102** is then expelled through applicator **106** to a desired area—e.g., a tooth gum margin of a user—by squeezing resilient portion **104** to cause the composition to flow from resilient portion **104** through applicator **106**.

[0059] As noted above, system **100** may be configured to apply a composition to a specific area within an oral cavity. In this case, applicator **106** may have a desirably small cross-section across applicator **106**. In accordance with specific examples of the present invention, a cross-sectional dimension, taken along line A-A, is about 0.001" to about 0.2", preferably about 0.05" to about 0.01", and more preferably about 0.06" to about 0.09".

[0060] Resilient portion **104** is designed to fit comfortably between two fingers (e.g., a thumb and an index finger) of a user, such that the composition is expelled by pressing the two fingers, on opposite sides of portion **104**, together. In accordance with various examples of the invention, portion **104** has a cross-sectional dimension, taken along line B-B, of about 0.1" to about 2", preferably about 0.25" to about 1", and more preferably about 0.4" to about 0.6".

[0061] A single-dose size may vary in accordance with several factors, such as the particular active ingredient, the dilution of the composition, and the like. Exemplary dose sizes for purpose of illustration range from about 0.5 mg to about 8 mg, preferably about 1 mg to about 7 mg, and more preferably about 2 mg to about 5 mg.

[0062] Method of Measurably Improving Oral Health

[0063] A method of measurably improving oral health includes applying a composition including one or more of the active ingredients described herein to a surface and maintaining the composition in contact with the surface for an extended period of time.

[0064] The composition may be applied using a variety of methods such as with a swab, with a syringe, or using any other means capable of dispensing the composition and applying a thin film of gel on the teeth and gums. In accordance with various aspects of this embodiment, the composition is selectively applied using system **100**. More particularly, composition **102** is applied though chute **106** to, e.g., a tooth/gingiva interface, such that the composition contacts both supragingival and subgingival areas where plaque and tartar is likely to form. Unlike most methods of promoting oral health, the method of this embodiment allows for direct, selective application of the composition to desired areas of a surface. Thus, less composition may be required to perform the task of measurably improving oral health, because the composition is not ubiquitously applied to an oral cavity.

[0065] In accordance with one aspect of this embodiment, a measurable difference of a gingivitis index (e.g., the Loe and Silness Gingival Index (1963)) is obtained by using the system of the present invention. More particularly, a measurable difference in the GI is obtained by applying a composition, e.g., from within the container, to an area (e.g., proximate an inflamed gum tissue, such as at the gum/tooth margin near the inflamed area). In accordance with various aspects of this embodiment, a single dose of the composition is applied after brushing teeth, flossing between teeth, and/or rinsing an oral cavity, and is applied such that the composition remains in contact with the affected area for an extended period of time. By way of particular example, the composition can be applied at before an extended period of rest or bedtime to mitigate disruption of the composition/surface interface and to facilitate maintaining the composition in contact with the surface for an extended period.

[0066] In accordance with another aspect, a measurable difference of a plaque index, e.g., the Turesky Modification (1970) of the Quiqley and Hein Plaque Index (PI) is obtained by using the method of the present invention.

[0067] In accordance with another aspect, the method is used as described above in connection with obtaining a measurable difference in the GI.

[0068] In accordance with yet a further aspect of this exemplary embodiment, a measurable difference in a tartar index—e.g., the Volpe-Manhold Index (V-MI)—is obtained by using the method of the present invention as described herein. As used herein, a "measurable difference" means a reduction in one or more of the selected indices of on the order of about 20% or more. In accordance with yet another embodiment a measurable improvement in a stain index—e.g., the Lobene Stain Index (SI)—is obtained using the system of the present invention.

SPECIFIC EXAMPLES

[0069] The following non-limiting examples illustrate measurable improvements in various indices using the method in accordance with various embodiments of the invention. These example are merely illustrative, and it is not intended that the invention be limited to the examples. Compositions for use in accordance with the present invention may include the ingredients listed below as well as additional and/or alternative inert materials, preservatives, and other constituents typically found in compositions for promoting oral health. In the case where exemplary inert materials and/or preservatives are listed, these ingredients are merely exemplary, and it is understood that other similar ingredients may be substituted for the materials listed in the examples below.

Example 1

Reduction in V-MI

[0070] A pale light pink viscous gel, having a viscosity of about 40,000 cp, with cinnamon-clove characteristic odor and taste is formed by admixing the following ingredients in the amounts shown.

TABLE 1

Ingredient	Supplier	Weight %	Exemplary Wt % Range
Purified Water	Copacker	91.603	80-99
Glycerin USP	Acme-Hardesty	5.000	0.01-15
HEC 250 HX	Hercules-Aqualon	2.000	0.01-10
Sorbitol	Roquette	0.050	0.001-0.5
Sucralose	Tate & Lyle	0.400	0.001-1.5
Cetylpyridinium Chloride	Dastech	0.100	0.001-1
Zinc Gluconate USP	American Ingredients/ Pharmachem Inc.	0.592	0.001-1.5
Cinnamon (Oil)	Berje	0.250	0.001-2
Clove (Oil)	Berje	0.005	0.001-2
Red #40 (1% sol.)	Pylam	0.00099	0.000001-0.001

[0071] A clinical study comparing the composition of Example 1 to a placebo and a commercial mouth rinse including CPC was conducted. Each group started with 25 people. At the conclusion of the 6 week test period, there was an observable/measurable difference in the quality and

thickness of calculus in the group using the composition of Example 1, compared to the placebo and the mouth rinse. A significant disruption of calculus bridges or masses of calculus was observed in subjects using the composition of Example 1.

[0072] A visibly noticeable amount of tartar was removed from the surface of the teeth after the six-week period.

Example 2

Reduction in GI

[0073] A clinical study comparing the composition of Example 1 to a placebo and a mouth rinse including CPC was conducted. Each group started with 25 people. At the conclusion of a six week test period, there was an observable/measurable difference in the improvement of the GI for the group using the composition of Example 1, compared to the groups using the placebo and the rinse. The difference was statistically significant (p value≦0.05, based on ANCOVA results, adjusting for baseline value and multiple comparisons) in both absolute and percent improvement of GI between the groups.

Example 3

Reduction in PI

[0074] A clinical study comparing the composition of Example 1 to a placebo and a mouth rinse including CPC was conducted. Each group started with 25 people. At the conclusion of a six week test period, there was an observable/measurable difference in the improvement of the PI for the group using the composition of Example 1, compared to the groups using the placebo and the rinse.

[0075] Although exemplary embodiments of the present invention are set forth herein, it should be appreciated that the invention is not so limited. Various modifications, variations, and enhancements in composition and method set forth herein may be made without departing from the spirit and scope of the present invention.

I claim:

1. A method to measurably improve an oral health index comprising:

a. providing at least one system, the at least one system including a composition within a container wherein the composition comprises an active ingredient for measurably improving oral health; and

b. applying the composition to a surface within an oral cavity;

wherein the oral health index comprises at least one of a gingival index, a plaque index and a calculus index and wherein the viscosity of the composition is greater than about 20,000 centipoise.

2. The method of claim 1, wherein the viscosity of the composition is about 20,000 centipoise to about 250,000 centipoise.

3. The method of claim 2, wherein the viscosity of the composition is about 25,000 to about 100,000 centipoise.

4. The method of claim 3, wherein the viscosity of the composition is about 30,000 to about 50,000 centipoise.

5. The method of claim 1, wherein the active ingredient comprises at least one of cetylpyridinium chloride, dicalcium phosphate dehydrate, hydrogen peroxide, sanguinaria extract, sodium bicarbonate, sodium lauryl sulfate, stannous fluoride, zinc salts such as zinc chloride, zinc acetate, zinc citrate, and zinc gluconate, alkyl dimethyl amine oxide, alkyl dimethyl glycine, eucalyptol, menthol, methyl salicylate, thymol, sodium citrate, peppermint oil, sage oil, polymethylsiloxane, polxamer, and stannous pyrophosphate.

6. The method of claim 1, further comprising a kit including a plurality of systems.

7. A method to measurably reduce existing tartar comprising:

a. providing a system including a composition within a container, the composition including an active ingredient and a thickening agent for measurably reducing existing tartar and the container including a resilient vial and a spout for targeted delivery of the composition; and

b. applying the composition to a surface within an oral cavity.

8. The method of claim 7, wherein the viscosity of the composition is about 20,000 centipoise to about 250,000 centipoise.

9. The method of claim 8, wherein the viscosity of the composition is about 25,000 to about 100,000 centipoise.

10. The method of claim 9, wherein the viscosity of the composition is about 30,000 to about 50,000 centipoise.

11. The method of claim 7, wherein the active ingredient comprises at least one of cetylpyridinium chloride, dicalcium phosphate dehydrate, hydrogen peroxide, sanguinaria extract, sodium bicarbonate, sodium lauryl sulfate, stannous fluoride, zinc salts, alkyl dimethyl amine oxide, alkyl dimethyl glycine, eucalyptol, menthol, methyl salicylate, thymol, sodium citrate, peppermint oil, sage oil, polymethylsiloxane, polxamer, and stannous pyrophosphate.

12. The method of claim 7, wherein the thickening agent comprises at least one of hydroxyethylcellulose, hydroxypropyl methylcellulose, carrageenan, guar gum, methylcellulose, and methyethylecellulose.

13. The method of claim 12 wherein the thickening agent is present in an amount of about 0.01 wt % to about 10 wt %.

14. The method of claim 13, wherein the thickening agent is present in an amount of about 0.1 wt % to about 7 wt %.

15. The method of claim 14, wherein the thickening agent is present in an amount of about 1 wt % to about 5 wt %.

16. A method to measurably improve an oral health index comprising the steps of:

a. providing at least one system, the at least one system including a composition within a container, wherein the composition comprises a plurality of active ingredients for measurably improving oral health and a thickener;

b. applying the composition to a surface within an oral cavity; and

c. maintaining the composition in contact with the surface for an extended period of time;

wherein the oral health index comprises at least one of a gingival index, a plaque index and a calculus index.

17. The method of claim 11, wherein the viscosity of the composition is greater than about 20,000 centipoise.

18. The method of claim 13, wherein the viscosity of the composition is about 25,000 to about 100,000 centipoise.

19. The method of claim 14, wherein the viscosity of the composition is about 30,000 to about 50,000 centipoise.

20. The method of claim 16, wherein the active ingredient comprises at least one of cetylpyridinium chloride, dicalcium phosphate dehydrate, hydrogen peroxide, sanguinaria extract, sodium bicarbonate, sodium lauryl sulfate, stannous fluoride, zinc salts such as zinc chloride, zinc acetate, zinc citrate, and zinc gluconate, alkyl dimethyl amine oxide, alkyl dimethyl glycine, eucalyptol, menthol, methyl salicylate, thymol, sodium citrate, peppermint oil, sage oil, polymethylsiloxane, polxamer, and stannous pyrophosphate.

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