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(54) **METHOD FOR IMPROVING ORAL HEALTH**

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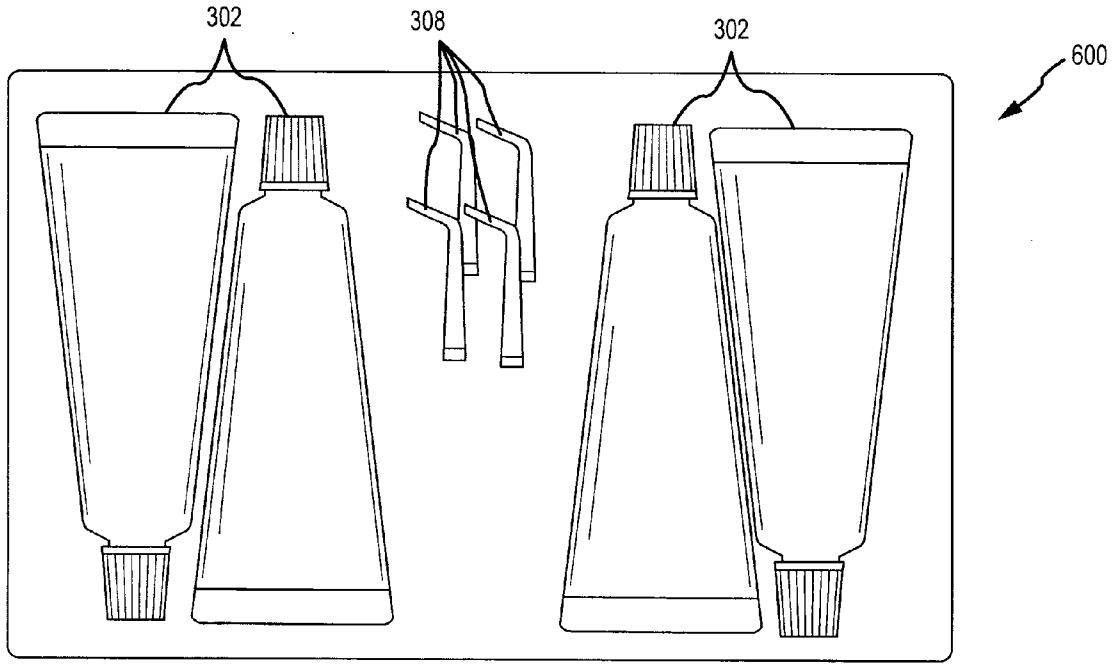
(57) **ABSTRACT**

A composition for improving oral health, a system including the composition, a kit including multiple systems, a method of using the composition, system, and kit, and a method of forming the composition, system, and kit are disclosed. The composition is designed to maintain contact with a portion of an oral cavity for an extended period of time to, for example, prevent or reduce bacteria growth, plaque and calculus buildup.



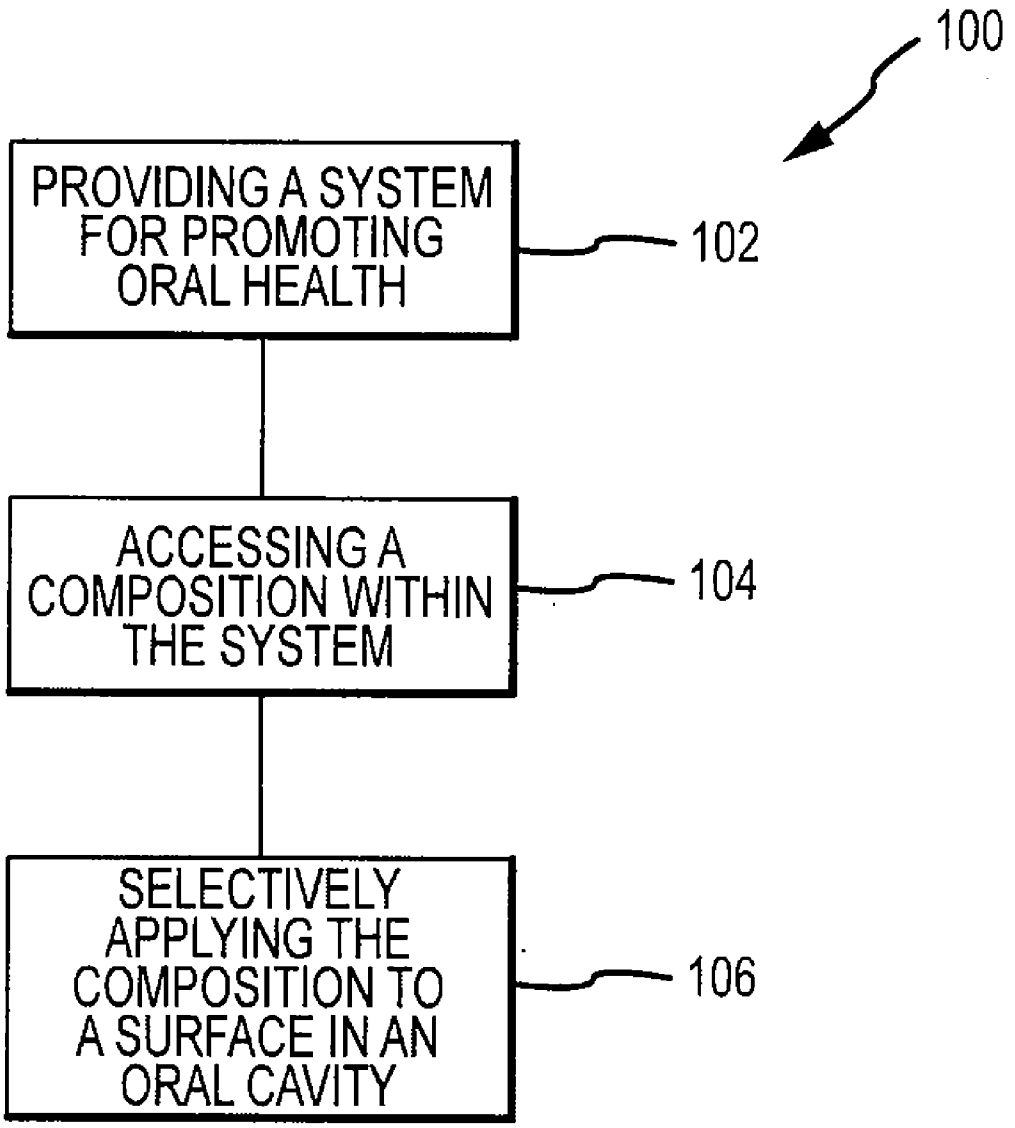

100
PROVIDING A SYSTEM FOR PROMOTING ORAL HEALTH
102
ACCESSING A COMPOSITION WITHIN THE SYSTEM
104
SELECTIVELY APPLYING THE COMPOSITION TO A SURFACE IN AN ORAL CAVITY
106

FIG.1

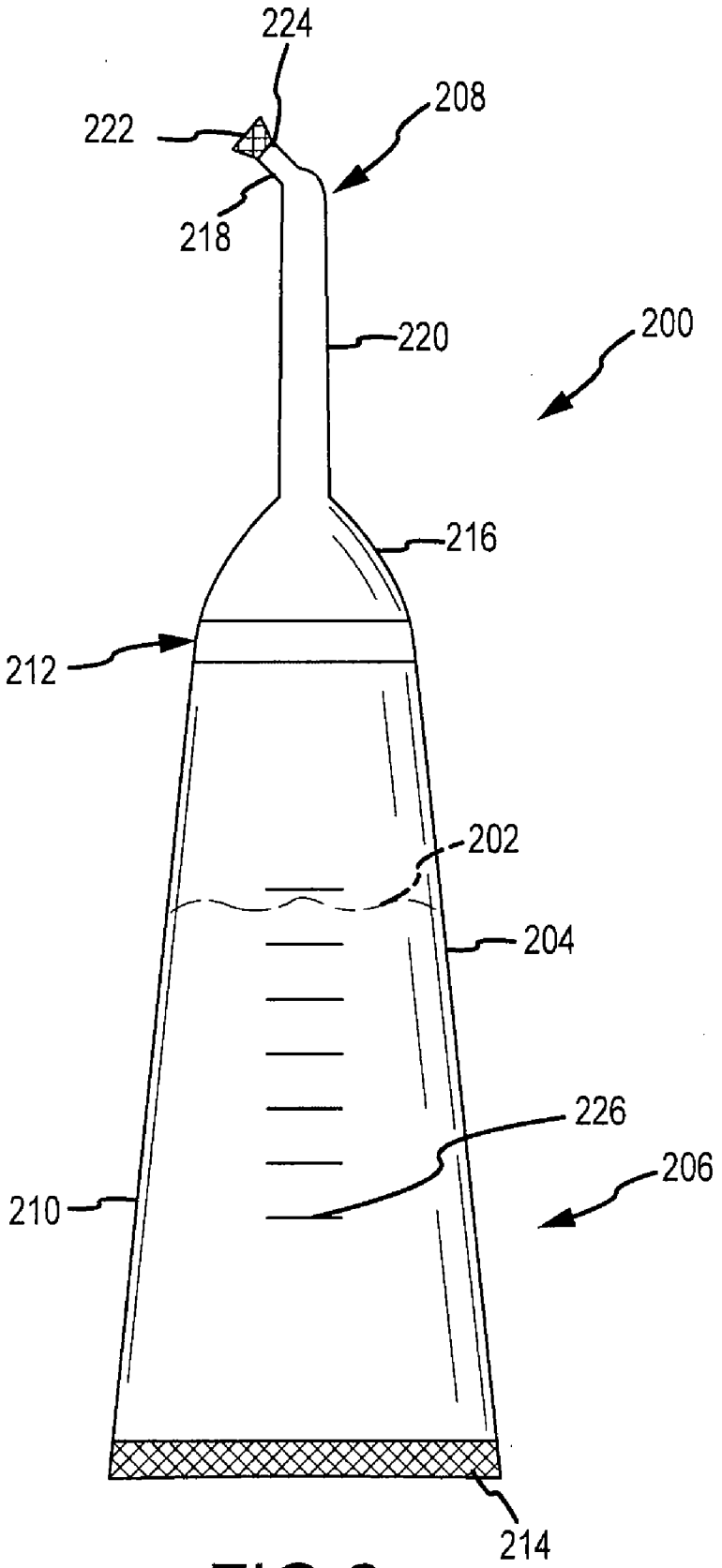


FIG.2

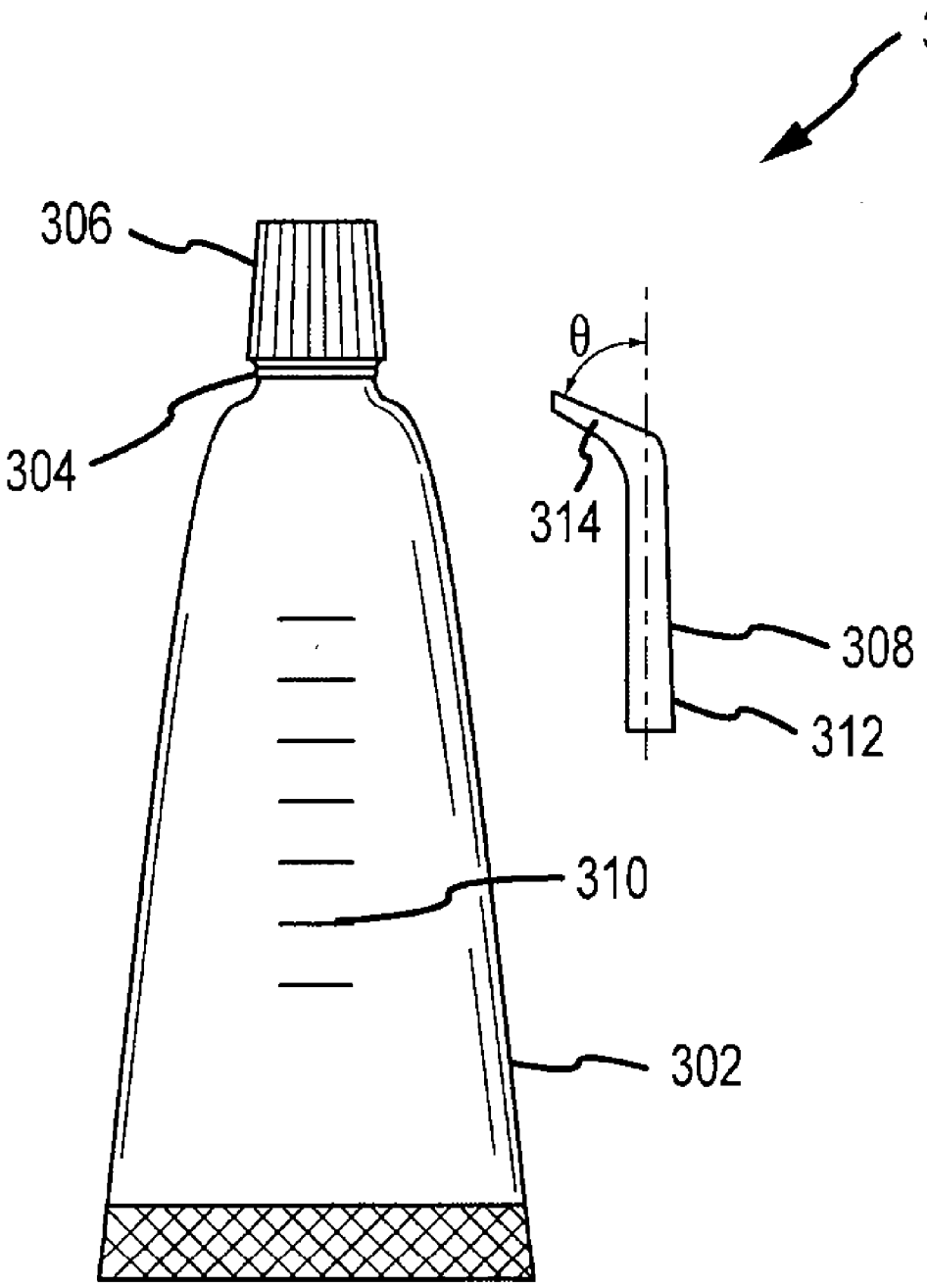


FIG.3

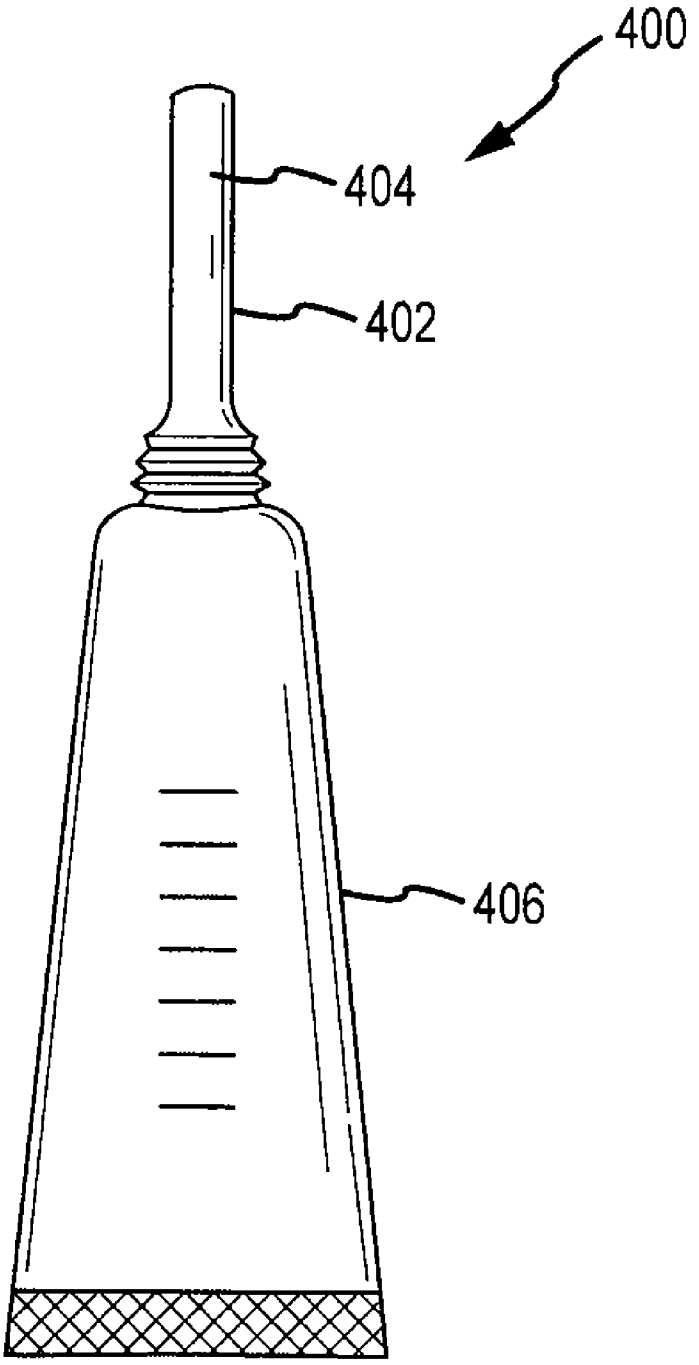


FIG.4

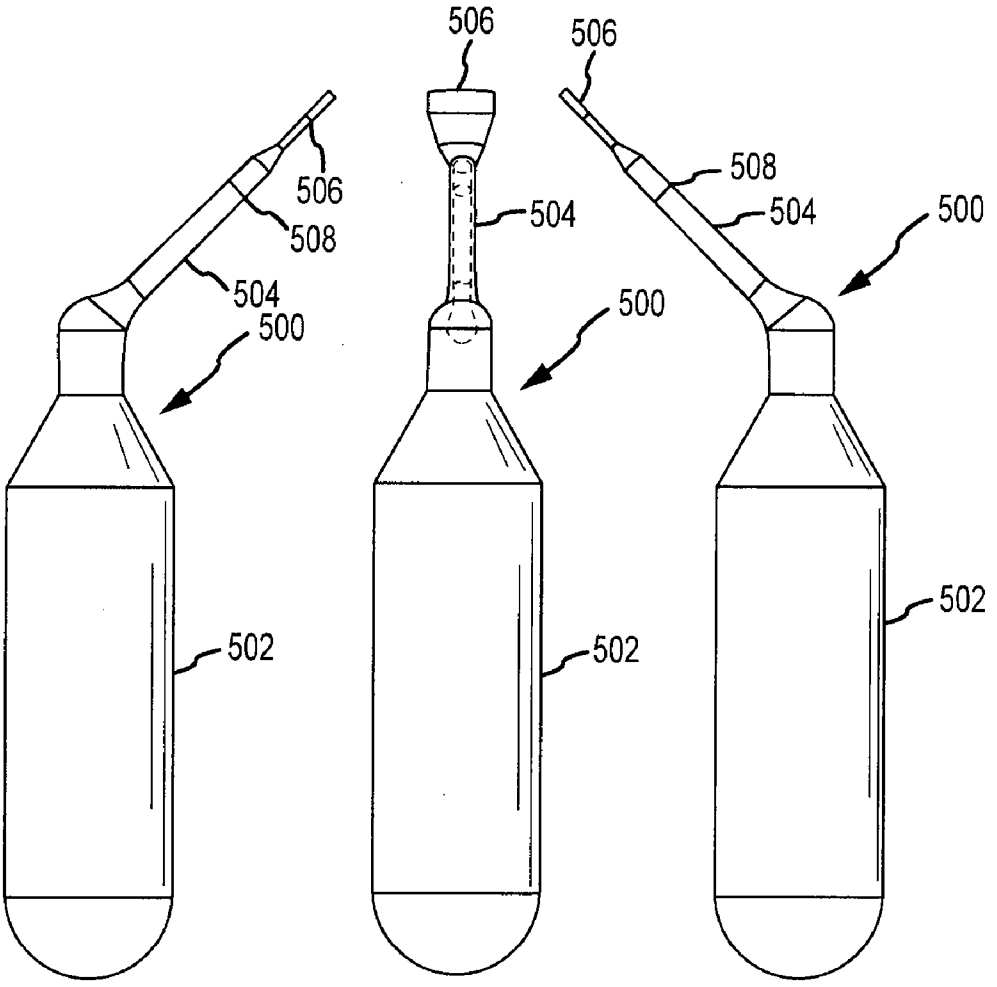


FIG.5A FIG.5B FIG.5C

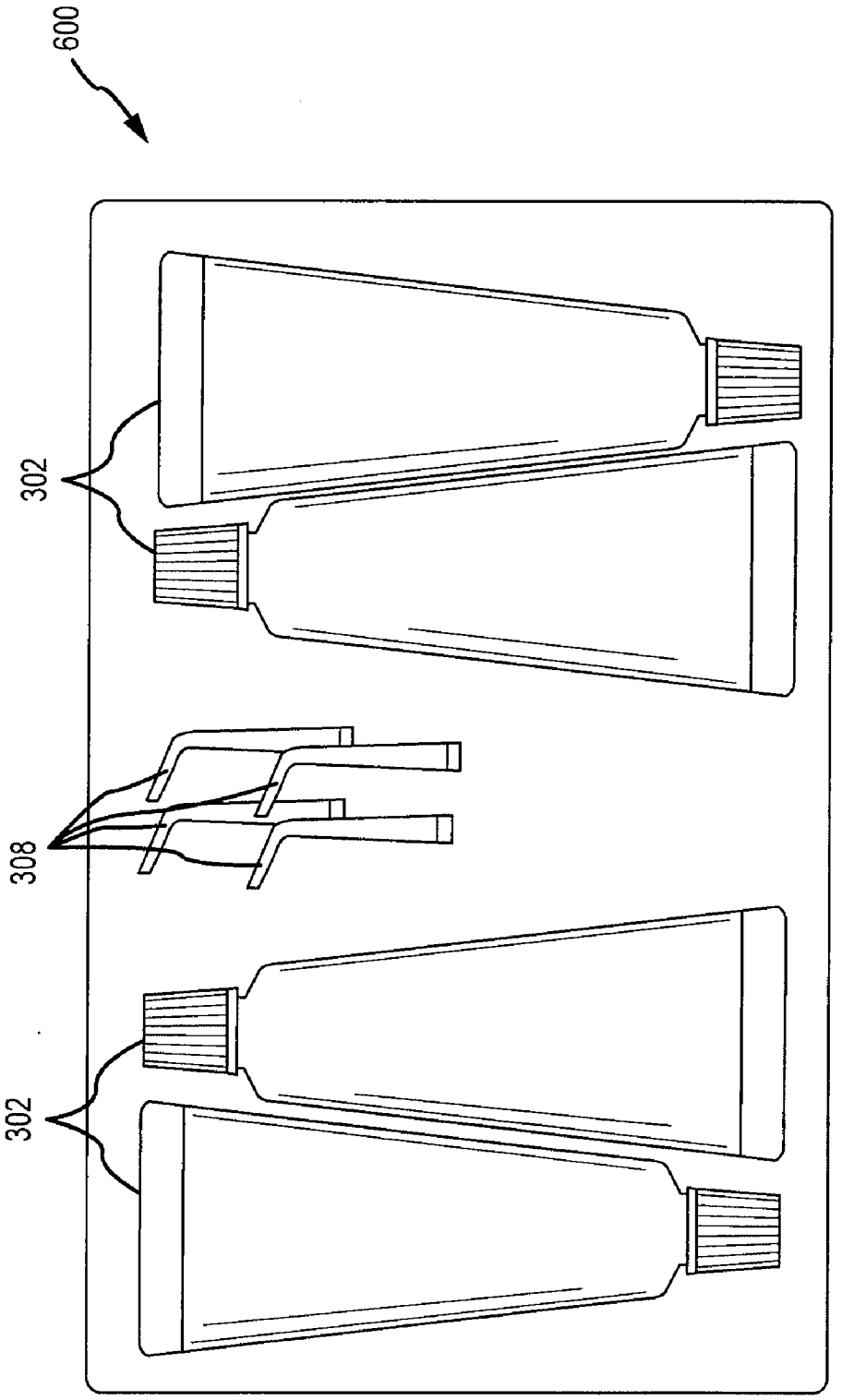


FIG.6

METHOD FOR 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 improving oral health. More particularly, the invention relates to methods for an amount of bacteria, gingivitis, halitosis, periodontitis, bleeding, plaque, tartar, tooth discoloration and/or the like.

BACKGROUND OF THE INVENTION

[0003] Unfortunately, poor oral health affects millions of people every year. Poor oral health may result in symptoms ranging from bad breath, tooth decay, and tooth discoloration, to more serious health problems, such as gingivitis, periodontitis, and even general health problems, such as 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, gum bleeding, 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 orthodontia (e.g., braces), dentures, bridges, crowns, fillings, 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. 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 can, in turn, lead to gum bleeding, tooth decay, gingivitis, periodontitis, and other health problems.

[0008] Gingivitis is the beginning stage of periodontitis and is often caused by the long-term effects of plaque and tartar buildup. Gingivitis is often characterized by red, swollen gums. A periodontal probe will often measure about 3 mm 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.

[0009] 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.

[0010] In addition to the health concerns, tartar is a cosmetic problem due to its discoloration of teeth. Namely, teeth can become yellowish or brownish color. Moreover, because the surface of tartar is rough and porous, the tartar absorbs colors from other sources (e.g., coffee, tea, tobacco, smoke, red wine and the like), and thus the presence of tartar exacerbates cosmetic tooth discoloration typically associated with such other sources.

[0011] Typical methods of preventing tartar buildup include brushing with tartar control toothpaste and flossing—e.g., daily. Although such toothpastes, if used regularly, may prevent buildup of additional tartar, the toothpastes are not thought to be effective at removing existing tartar from tooth enamel and dental device surfaces.

[0012] 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. Furthermore, various methods for inhibiting tartar may cause damage to tooth enamel and/or to dental devices.

[0013] Accordingly, improved methods improving oral health, such as, for example, reducing an amount of bacteria, other microorganisms, tartar, plaque, gingivitis, periodontitis, and the like are desired.

SUMMARY OF THE INVENTION

[0014] In accordance with various embodiments and aspects of the present invention, methods for improving oral health are provided. Exemplary methods provide a relatively inexpensive and safe treatment for facilitating maintenance and improvement of oral health and/or hygiene, such as through the prevention and/or measurable reduction of an amount of microorganisms, gingivitis, periodontitis, bleeding, plaque, tartar and/or the like. In addition, exemplary oral health methods are relatively easy to use or perform, do not require a visit to a dentist office, and do not damage the surface of enamel or dental devices.

[0015] In accordance with various embodiments of the invention, a method of improving oral health includes providing a composition and selectively applying the composition to a surface within an oral cavity.

[0016] In accordance with exemplary embodiments of the invention, a method of improving oral health includes providing a system, including a composition within a container, accessing the composition, and selectively applying the composition to a surface within an oral cavity.

[0017] In accordance with further embodiments of the invention, a method of improving oral health includes providing a kit, including a plurality of systems, each system including a composition within a container, accessing the composition, and selectively applying the composition to a surface within an oral cavity.

[0018] In accordance with various embodiments of the invention, the step of providing a system includes providing a viscous composition, including at least one active ingredient to promote and/or maintain oral health, and a container configured to dispense the viscous composition.

[0019] In accordance further embodiments, the composition is designed to maintain the active ingredient(s) in contact with a surface for an extended period of time. Suitable active ingredients include cetylpyridinium chloride (CPC), zinc salts, other antimicrobial agents, and other ingredients to measurably improve oral health.

[0020] In accordance with yet further embodiments, the viscous composition further comprises a carrier having a thickening agent, wherein the composition is configured to maintain the active ingredient(s) in contact with a surface for an extended period of time. Exemplary thickening agents suitable for use in the viscous composition include hydroxyethylcellulose and other pharmaceutically acceptable thickeners. Exemplary compositions have a viscosity greater than about 20,000 centipoise (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.

[0021] In accordance with further embodiments, the container configured to dispense the composition includes an expulsion or vessel portion, configured to store and facilitate expulsion or other like transfer of the composition, and an applicator portion, configured to receive the composition and to facilitate delivery of the composition to a surface within an oral cavity. In accordance with various aspects of exemplary embodiments, the applicator portion includes an angled spout to facilitate targeted delivery of the composition—e.g., to a gum/tooth interface. In accordance with further aspects, an exemplary container is configured with an access/closure portion to maintain the composition within the container. In accordance with additional aspects of this embodiment, an exemplary container encases multiple doses of the composition. Alternatively, an exemplary container may encase a single dose. In accordance with yet further aspects, the container is configured to facilitate delivery of the composition to specific portions within an oral cavity.

[0022] In accordance with other embodiments of the invention, the composition includes one or more active ingredients that are positively charged in the composition. The active ingredients are drawn to negatively charged areas within an oral cavity (e.g., teeth, gums, and dental devices) and thus provide added efficacy compared to neutral or negatively charged active ingredients.

[0023] In accordance with further embodiments of the invention, a method includes applying the composition before an extended period of rest. In accordance with aspects of this embodiment, the composition is designed to stay in contact with a surface for an extended period of time, during which saliva production is relatively low. In accordance with further aspects, the composition is applied when activities, such as talking, chewing, and the like, that may cause the composition to be dislodged from a surface are minimized.

[0024] In accordance with further embodiments, a composition includes a broad spectrum antimicrobial agent and a calculus inhibitor that also functions as an antimicrobial agent.

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 block diagram of an exemplary method for improving oral health in accordance with an exemplary embodiment of the invention;

[0027] FIG. **2** illustrates an exemplary system for measurably improving oral health in accordance with an exemplary embodiment of the invention;

[0028] FIG. **3** illustrates another exemplary system for expulsion and application of a composition to a surface within an oral cavity in accordance with an exemplary embodiment of the invention;

[0029] FIG. **4** illustrates yet another exemplary system for use in accordance with various embodiments of the invention;

[0030] FIGS. **5**A-**5**C illustrate, respectively, a left view, a front view, and a right view of an exemplary container for use in accordance with an exemplary embodiment of the invention; and

[0031] FIG. **6** illustrates an exemplary kit, including a plurality of systems, for use in accordance with yet another exemplary embodiment of the invention.

[0032] Elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale. The dimensions of some of the elements in the figures may be exaggerated relative to other elements to help to improve understanding of embodiments of the present invention.

DETAILED DESCRIPTION

[0033] The present invention provides methods for improving oral health. More particularly, the invention provides methods of using a composition, system, and/or kit to, for example, reduce bacteria and other microorganisms, calculus, plaque, halitosis, gingivitis, bleeding, and the like. In general however, the methods disclosed herein may be suitable for improving other oral health ailments. The methods for improving oral health disclosed herein can be used to improve oral health of various animals, and are particularly well suited for humans by application to a surface of an oral cavity.

[0034] As used throughout this application, the term "surface" includes any surface on which bacteria and other

microbials, plaque, tartar, or gum disease may form. Exemplary surfaces include teeth (both supragingival and subgingival), gums, and dental devices, such as orthodontia (e.g., braces, retainers, etc.), dentures, bridges, crowns, fillings, and the like. Further, as used herein, the term "measurably improve" means a measurable difference between an amount measured without use of the composition of the present invention and with or after use of the composition. The measurements may be compared for the same surface (e.g., before and after) or between control and test groups.

[0035] The invention is described herein in terms of various functional components, compositions and processing steps. It should be appreciated that such components, compositions and steps may be realized by any number of structural components and compositional constituents configured to perform the specified functions. For example, the methods herein may employ various compositions and containers for use with systems and kits for improving oral health; the specific examples as described herein are merely indicative of exemplary applications for the invention.

[0036] In accordance with exemplary embodiments, with reference to FIG. **1**, a method **100** for improving oral health includes providing a composition, system (a composition within a container), and/or kit (a plurality of systems) (step **102**); accessing the composition if within a system (step **104**); and selectively applying the composition to a surface within an oral cavity (step **106**).

[0037] FIG. **2** illustrates a system **200** for use in accordance with various embodiments of the present invention. For example, system **200** can be used in connection with method **100** to facilitate prevention and/or reduction of gingivitis, periodontitis, bleeding, plaque, tartar, other general health problems and/or otherwise improve oral health. In accordance with various exemplary aspects of the illustrated embodiment, system **200** includes a composition **202** and container **204** for selectively applying composition **202** to a surface within an oral cavity.

[0038] In accordance with various exemplary embodiments, a composition (e.g., composition **202**), suitable for use with systems (e.g., systems **200**, **300**, **400**) of the present invention comprises an active ingredient and a viscous carrier. In this case, composition **202** is configured to maintain the active ingredient in contact with a surface of an oral cavity for an extended period of time to allow the active ingredient(s) to remain in contact with the surface for an extended period.

[0039] 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, domiphen 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.

[0040] In accordance with various embodiments of the invention, the active ingredient(s) are positively charged within the solution to facilitate migration of the active(s) through the solution and to the surface, which is typically negatively charged. Because surfaces (e.g., gums, teeth, devices, plaque, tartar, and the like) within an oral cavity are typically negatively charged, the positively charged active ingredients are drawn toward the surface(s) an may bond thereto.

[0041] In accordance with further embodiments of the invention, at least one of the active ingredients is a broad spectrum antimicrobial agent, such as CPC, that reduces and/or mitigates bacterial and other microbial growth.

[0042] In accordance with further aspects, the composition includes a calculus inhibitor, such as zinc ions. In this case, the zinc ions have the added advantage of functioning as another antimicrobial agent.

[0043] 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.

[0044] In accordance with one preferred exemplary embodiment, the active ingredient(s) include CPC. In one case, CPC is present in an amount of about 0.001% to about 1%, in an amount of about 0.01% to about 0.5%, or even in an amount of about 0.05% to about 0.25% or about 0.045% to about 0.1%. In accordance with another exemplary embodiment, the active ingredient(s) also include zinc gluconate. In one case, zinc gluconate is present in an amount of about 0.001% to about 2%, in an amount of about 0.01% to about 1.0%, or even in an amount of about 0.05% to about 0.75%.

[0045] In accordance with an exemplary embodiment, the composition also includes a thickener to obtain the desired viscosity. Suitable thickening agents include substances which increase the viscosity of composition **202**, cause composition **202** to gel or coagulate, or the like, such as food-grade or pharmaceutical-grade thickeners, including, for example, hydroxyethylcellulose, hydroxypropyl methylcellulose, carrageenan, guar gum, methylcellulose, methyethylecellulose, acceptable non-ionic thickeners, and the like. The thickener may be present in an amount of about

0.01% to about 10%, in an amount of about 0.1% to about 7%, or even in an amount of about 1% to about 5% or about 0.5% to about 3%.

[0046] Composition **202** 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 composition **202** in a liquid form and may help maintain a desired viscosity. In accordance with specific aspects, glycerin facilitates maintaining one or more of the active ingredients in an ionic form and/or facilitates the transport of the active ingredients through composition **202**. This can be particularly advantageous when the active ingredients and the surface(s) are oppositely charged.

[0047] The composition may also include a diluent. Exemplary diluents suitable for use with the present composition include sorbitol, xylitol, mannitol, 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%.

[0048] Composition **202** may also include sugar alcohols such as sorbitol and xylitol, monnital, lactitol, and the like that act as a sweetener and also as a humectant and/or emulsifier and/or diluent. When used, sorbitol or other sugar alcohol can be present in an amount of about 0.001% to about 0.5%, in an amount of about 0.01% to about 0.1%, or even in an amount of about 0.025% to about 0.075%. Compositions in accordance with the invention may alternatively include a greater percentage of sugar alcohol(s).

[0049] Composition **202** may also include a natural or artificial sweetener such as cyclamates, sucralose, saccharin (e.g., sodium or calcium), ace-k, or aspartame which, when included in composition **202**, can be present in an amount of about 0.001% to about 1.5%, in an amount of about 0.01% to about 1%, or even in an amount of about 0.25% to about 0.75%.

[0050] Colorants may also be added to composition **202**. For example, composition **202** can include colorants, such that when composition **202** is applied to or proximate the gingiva, composition **202** has a color indicative of healthy gingiva—e.g., composition **202** can be pink in color. Such a composition having a color indicative of healthy gingiva can provide added incentive to users to continue using composition **202**, which in turn promotes improved health care and hygiene. Colorants may be present in any desired amount. For example, the colorants may include Red #33 and/or Red #40, available from Pylam in an amount of about 0.000005% to about 1%, preferably about 0.00050% to about 0.5%, and more preferably about 0.001% to about 0.1%. Additionally or alternatively, colorants, which are indicative of flavor may be added to the composition. Examples include FD&C Blue #1, D&C Green #5, FD&C Yellow #5, and FD&C Yellow #6.

[0051] Composition **202** may also include flavorants such as cinnamon oil, clove oil, mints, anise, citrus, fruits, and the like, which, when included in the formula are present in an amount of about 0.01% to about 2%, in an amount of about 0.01% to about 1%, or even in an amount about of about 0.1% to about 0.5%.

[0052] Essential oils such as cinnamon bark oil and clove bud oil may be particularly advantageous because they exhibit additional desirable qualities. For example, cinnamon bark oil exhibits antibacterial, antiseptic, antiviral, antispasmodic, antifungal, sedative and analgesic properties and clove bud oil has local anesthetic, antiseptic, antibacterial, and stimulating properties.

[0053] Composition **202** is configured to maintain contact with a surface for an extended period of time, which has several advantages over traditional compositions. Composition **202** preferably exhibits good microadhesion, and moreover, composition **202** preferably is quite viscous. As such, in general, relatively small amounts of composition **202** and consequently the active agent(s) can be used to effectively provide oral health care or treatment. Additionally, the relatively high viscosity allows for relatively select placement of the composition on a surface.

[0054] Exemplary compositions have a viscosity greater than about 20,000 cp, preferably greater than 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 cp to about 250,000 cp, preferably about 25,000 cp to about 100,000 cp, and more preferably about 30,000 cp to about 50,000 cp, and yet more preferably about 35,000 cp 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.

[0055] In accordance with other exemplary embodiments, composition **202** includes multiple active ingredients in a carrier. For example, composition **202** can include a plurality of any active ingredients and a carrier in the weight percents disclosed herein. By way of one example, one active may include a broad spectrum antimicrobial agent and one active may include a calculus inhibitor and/or another antimicrobial agent. Composition **202** may also include any of the optional ingredients, such as thickeners, sweeteners, flavorants, and colorants as set forth herein. For example, in accordance with an exemplary embodiment, composition **202** includes CPC and zinc gluconate as the active ingredients, wherein the CPC is present in an amount of about 0.001% to about 1%, in an amount of about 0.01% to about 0.5%, or even in an amount of about 0.05% to about 0.25% or about 0.045% to about 0.1%; and wherein the zinc gluconate is present in an amount of about 0.001% to about 2%, in an amount of about 0.01% to about 1.0%, or even in an amount of about 0.05% to about 0.75%.

[0056]]. In accordance with other exemplary embodiments, composition **202** includes one or more active ingredients and a colorant indicative of healthy gingival, wherein the color of composition **202** is more than merely decorative; it also 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 composition **202**, that healthy gingival is achieved.

[0057] A pH of a composition in accordance with various embodiments of the invention is preferably between about 4-10, preferably about 4-7, and more preferably about 5-5.4.

[0058] Composition **202** may be formed by adding a humectant (e.g., glycerin) to a first mixing vessel and the adding a thickener (e.g., hydroxyethylcellulose) to the

humectant and mixing until a uniform, lump-free slurry forms. The slurry should not sit for too long at this stage, or it may become cement-like in texture and viscosity. In a second mixing vessel, add a diluent (e.g., water) and add the humectant/thickener slurry slowly (over a period of a few hours) to the diluent and mix until a smooth mixture is obtained. Once the gum is hydrated, add any sugar alcohol, sweetener, and colorant to the mixture and mix until each is dissolved. Finally, add any oils and mix until the oils are dispersed in the solution and add the actives and mix until dispersed.

[0059] Referring again to FIG. **2**, container **204**, for use with various embodiments of the invention, is configured for containment and temporary storage of composition **202**, i.e., storage until initiation of the treatment process, and for expulsing, transferring or otherwise forcing composition **202** to a surface to achieve improved oral health. Container **204** can be configured in various manners for application of composition **202** to a surface. For example, container **204** can comprise various sizes, volumes, shapes and configurations for facilitating transfer of composition **202** to a surface, depending upon, for example, the purpose for which composition **202** is being applied.

[0060] In the case of prophylaxis or reduction in microorganisms, gingivitis, periodontitis, bleeding, plaque, tartar, and the like, it may be desirable to have a multi-dose applicator for repeated (e.g., daily) application of composition **202**. Alternatively, a single-dose applicator may be desirable for limited application (e.g., travel), or for application of composition **202** to specific problem areas, such as targeted application to diseased or infected areas or dental devices within an oral cavity.

[0061] In accordance with specific examples of various embodiments, container **204** is configured to store about seven doses, about four doses, about two doses, or about one dose. However, the invention is not necessarily limited to these container sizes.

[0062] A dose size may vary in accordance with several factors, such as the particular ingredients, the dilution of the composition, and the like. Exemplary dose sizes for purpose of illustration range from about 1 mg to about 6 mg, preferably about 2 mg to about 5 mg, and more preferably about 3 mg to about 4 mg.

[0063] With continued reference to FIG. **2**, container **204** includes expulsion or vessel portion **206**, configured to contain or store composition **202** and to facilitate expulsion of composition **202**, and applicator portion **208**, configured to receive composition **202** from expulsion portion **206** and to facilitate application or delivery of composition **202** to a selected oral cavity surface.

[0064] In accordance with particular aspects of this embodiment, portion **206** is formed of a resiliently deformable material that is capable of retaining and returning to its original shape when not under pressure. In accordance with other aspects, portion **206** is formed of material that does not return to its original shape. Exemplary resilient materials suitable for portion **206** include low density polyethylene material, high density polyethylene, medium density polyethylene, linear low density polyethylene, polyvinyl chloride, K resin, polyethylene terephthalate and copolyesters, polypropylene, surlyn, silicones and other thermostatics, metal or alloy, and the like. Portion **206** may be opaque, transparent, or semitransparent. An advantage of forming vessel portion **206** of transparent or semitransparent material is that an amount of composition **202** within vessel portion **206** can be ascertained when the portion is formed of such material. Material used to form vessel portion **206** may also include UV protection additives, colorants, or the like, and is preferably FDA-approved material.

[0065] In accordance with various embodiments of the invention, expulsion or vessel portion **206** includes resilient vial **210** and a neck **212**. Resilient vial **210** acts as a reservoir for composition **202** and also facilitates expulsion of composition **202** from system **200** when pressure is applied to an external surface of vial **210**. As illustrated, vial **210** may also include graduations **226** to, for example, illustrate a number of doses used and/or a number of doses remaining. Neck **212** is configured to couple applicator or spout portion **208**.

[0066] Although illustrated as substantially tubular, with a sealed end **214**, resilient vial **210** may be of any suitable shape or configuration. For example, vial **210** may be pyramidal, cone shaped, fluted, or have a rectangular cross section. Similarly, end portion **214** may be of any suitable shape or configuration, such as linear (e.g., a crimped or heat-sealed end) or the like. In general, preferred shapes of vial **210** conserve material used to form the vial, allow for easy dispensing of composition **202**, are easy to produce, and produce relatively little scrap material during production.

[0067] Container **204** can also be configured to allow a user to suitably control the rate of expulsion into applicator portion **208**. For example, in accordance with an exemplary embodiment, container **204** includes a transition region **216** to facilitate flow between vial **210** and applicator portion **208**. Transition region **216** may be of any suitable shape, such as frustro-conical, fluted, semi-spherical, and the like.

[0068] Applicator portion **208** may be formed of any of the material described above in connection with portion **206**. Portion **208** is suitably configured for selective and/or controlled delivery of composition **202** to a target area within an oral cavity interface **206**. In accordance with various embodiments of the invention, applicator portion **208** is configured to couple (e.g., detachably or otherwise) to expulsion portion **206**. Alternatively, portion **208** is configured as a molded or otherwise unitary structure with expulsion portion **206**, as described in more detail below. When separately formed, portions **206** and **208** may be coupled using screwed, press-fit, clamped or other techniques to permanently, semi-permanently or removably attached portions **206** and **208**.

[0069] In accordance with an exemplary embodiment, applicator portion **208** comprises a structure **220** to allow composition **202** to be forced through an applicator tip **218** and onto a surface within an oral cavity. Structure **220** may be passive and substantially rigid to allow composition to flow from portion **206** to tip **218**. Alternatively, structure **220** and/or applicator portion **208** may be configured as less-rigid to allow for expulsion of any remaining composition within applicator portion **208** to be squeezed or otherwise delivered or applied by applicator tip **218** onto a surface.

[0070] As illustrated structure **220** may form an angle of about zero degrees with respect to a centerline through

expulsion portion **206**. Alternatively, structure **220** may form other angles, ranging from about zero degrees to about 90 degrees. In further accordance with the illustrated embodiment, tip **218** forms an angle of about 45 degrees relative to the centerline of component **220**; however, tip **218** may suitably form other angles relative to component **220**.

[**0071**] Tip **218** is generally configured to facilitate placement and controlled flow of material dispensed from system **200**. Tip **218** may be substantially cylindrical. Alternatively, tip **218** may have a square, rectangular, ellipse, or other cross-sectional configuration. Tip **218** may also include a weakened section **224**, which may be formed, for example, by scarring a portion of tip **218**. Weakened section **224** may facilitate rupturing tip **218** at weakened section **224**, which in turn allows for a predicable cross section of tip **218** and thus a relatively predictable flow of material dispensed from system **200**. In accordance with one particular example, tip **218** includes a substantially constant cross-section, which makes the flow more predictable, even if tip **218** is ruptured away from weakened area **224**.

[**0072**] End portion **222** forms a sealed end at one end of tip **218**. In accordance with various embodiments of the invention, end portion **222** is flat and wider at an exterior portion than an interior portion, such that end portion **222** is wider in at least one direction than tip **218**. Having end portion **222** wider than tip **218** allows a user to grip end **222** to, for example, tear or sever tip **218** at weakened section **224**. However, end **222** may be alternatively configured as, for example, a semisphere or other suitable shape. Alternatively, tip **218** and end portion **222** may be configured, such that end **222** can reattach to tip **218**.

[**0073**] Spout portion **208** may be formed using a variety of materials, such as any of the materials described above in connection with vessel portion **206**. However, because spout portion **208** may be formed separately from vessel portion **206**, it need not be formed of the same material.

[**0074**] In accordance with one embodiment of the invention, vessel portion **206** and spout portion **208** are configured to sealably (and optionally rotatably) couple to each other. In the illustrated embodiment, portion **206** and **208** are threadedly coupled to each other. In accordance with other embodiments, one of portions **206** and **208** includes a protrusion and the other of portion **206**, **208** includes a recess to receive the protrusion, such that the protrusion and recess hold vessel portion **206** and spout portion **208** together, while optionally allowing the two portions to rotate about an axis, with respect to each other. In accordance with another embodiment of the invention, portions **206**, **208** are configured to allow vessel portion **206** and spout portion **208** to be detachably coupled to each other. In this case, neck **212** and spout **208** may be snap-fit together as described above, or portions **206** and cap **208** may engage using lug or interference-fit technology to sealably attach to each other.

[**0075**] FIG. **3** illustrates another system **300** for use in accordance with additional embodiments of the invention. As illustrated, system **300** includes a vessel portion **302**, including a neck **304**, a cap **306**, and a detachable applicator **308**. System **300** is similar to system **200**, except system **300** includes resealable cap **306** and detachable applicator **308**, rather than applicator portion **208**. System **300** may be formed of any of the materials noted above in connection with system **200**, and may include graduations **310** to indicated a number of doses used and/or a number of remaining doses, as described above.

[**0076**] Cap **306** can be removably attached to vessel portion **302** using a variety of techniques. For example, cap **306** may be threadedly attached to portion **302**. Alternatively, cap **306** and portion **302** may be coupled using snap-fit, lug, interference-fit technology, or similar technologies. In accordance with one specific example of this embodiment, neck **304** includes exterior threads and cap **306** includes interior threads to threadedly engage with neck **304**.

[**0077**] Similarly, applicator portion **308** may couple to vessel **302** in a variety of ways, such as threaded, snap-fit, lug, or similar type connections. By way of particular example, applicator **308** threadedly engages with an interior portion of neck **304**.

[**0078**] Applicator **308** includes a first portion **312** and a second or tip portion **314**. As illustrated, tip portion **314** is angled relative to a centerline first portion **312**; however such is not required for practice of the present invention. Exemplary angles range from about zero to about ninety degrees, and one example is preferably about forty-five degrees relative to the centerline.

[**0079**] FIG. **4** illustrates yet another system **400** in accordance with additional embodiments of the invention. System **400** is similar to system **300**, except system **400** includes an applicator **402**, rather than applicator **308**. Applicator **402** is similar to applicator **308**, except applicator **402** does not include an angled tip.

[**0080**] FIGS. **5**A-**5**C illustrate left, front, and right views of yet another system **500** in accordance with various embodiments of the invention. System **500** is similar to systems **200**-**400**, except system **500** is designed as a unitary system, having an integrated vessel **502** and spout **504**, including a severable end **506** and scarred section **508**.

[**0081**] Although not illustrated, systems in accordance with various embodiments of the invention may include tamper-resistant features. For example, system **200** may include a seal formed over neck **212**, using, for example plastic or foil glued to or otherwise adhered to a top portion of neck **212**. Alternatively, after spout portion **208** is attached to vessel portion **206**, the two portions may be fused together using heat sealing and/or adhesive techniques.

[**0082**] FIG. **6** illustrates a kit **600**, including multiple systems, in accordance with yet additional embodiments of the invention. As illustrated, kit **600** includes four systems; however, systems in accordance with other embodiments of the invention may include a different number, e.g., 1, 2, 4, 7, 10, or the like number of systems.

[**0083**] Referring back to FIG. **1**, providing a system, in accordance with step **102**, can include any method now known or hereinafter devised for filling a container with a fluid. With reference to FIG. **2**, a composition **202** can suitably be filled in one end of a container **204** and then sealed to maintain composition **202** within container **204**. Alternatively, with momentary reference to FIG. **3**, vessel **302** may be filled with composition **202** and then sealed with cap **306**. In addition, filling container **204** with composition

202 may include filling a single and/or daily dose of composition **202**, or multiple doses of composition **202**.

[**0084**] Accessing composition **202** within container **204**, in accordance with step **104**, suitably comprises removal of an access, closure device or component from container **204**. For example, in accordance with an exemplary embodiment, accessing composition **202** within container **204** comprises detachably removing an access component, e.g., end portion **222**, to provide an access to composition **202**.

[**0085**] Selectively applying composition **202** to a surface within an oral cavity, in accordance with step **106**, can suitably include expulsing, transferring or otherwise forcing composition **202** from a vial **210** to an applicator portion **208** of container **204**. For example, in accordance with an exemplary embodiment, composition **202** can be "squeezed" from an expulsion portion **206**, into applicator portion **208**, through an applicator tip **218**, and onto a targeted surface within an oral cavity.

[**0086**] In accordance with various embodiments of the invention, the composition is applied prior to an extended period of rest (e.g., 2, 4, 6, or more hours) and/or sleep. Applying the composition prior to such period is advantageous because activities such as chewing, talking, and the like, which may dislodge the composition from the surface are reduced. Furthermore production of saliva, which is a natural bactericidal agent, is often reduced at such times. Indeed bacteria growth during sleep is increased because of a lack of saliva flow.

[**0087**] Regular and/or systematic use of methods in accordance with various embodiments of the invention result in measurably improved oral health.

SPECIFIC EXAMPLES

[**0088**] The following non-limiting examples illustrate improvement in oral health using a system, kit, and method in accordance with various embodiments of the invention. These examples are merely illustrative, and it is not intended that the invention be limited to the examples. Kits, systems, and compositions 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

[**0089**] 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, as described above, in the amounts shown. The composition was sealed in system **500**, illustrated in FIG. **5**.

TABLE 1

Ingredient	Supplier	Weight %	Exemplary Wt % Range
Purified Water	Copacker	91.504	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	Dishman Pharmaceuticals	0.100	0.001-1
Zinc Gluconate USP	American International	0.592	0.001-1.5
Cinnamon Bark (Oil)	Spectrum	0.250	0.001-2
Clove Bud (Oil)	Spectrum	0.005	0.001-2
Red #40 (1% sol.)	Pylam	0.099	0.000005-1

[**0090**] At the end of a three-week period, there was an observed lessening or reduction of plaque quality, thickness, mass, and maturity; the lessening was greater (greater decrease) for those using the composition of Table 1, compared to a placebo. The observance that plaque quality was reduced is important because the presence of actively growing plaque bacteria (biofilm) is important in the development of inflammation, which leads to gingivitis and periodontitis.

[**0091**] In addition, at the end of the three-week period a lessening of the quality of calculus was also observed. A general improvement of gingival health was also observed. An extremely thin, slightly detached layer of epithelial cells was also found on the surface of attached gingival surfaces at the marginal ridge, close to the areas where plaque and tartar was likely disrupted off the teeth with subjects using the composition of Table 1, which indicated promotion of faster healing of gingival tissues.

[**0092**] Subjects at the end of the six-week period showed a reduction in gingivitis and plaque for those using the formula of Table 1 compared to a placebo.

Example 2

[**0093**] 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, as described above, in the amounts shown. The composition was sealed in system **500**, illustrated in FIG. **5**.

TABLE 2

Ingredient	Supplier	Weight %	Exemplary Wt % Range
Purified Water	Copacker	92.096	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	Dishman Pharmaceuticals	0.100	0.001-1
Cinnamon Bark (Oil)	Spectrum	0.250	0.001-2
Clove Bud (Oil)	Spectrum	0.005	0.001-2
Red #40 (1% sol.)	Pylam	0.099	0.000005-1

[**0094**] A clinical study showed a reduction of gingivitis for subjects using the formula of Table 2 for a six-week period compared to a placebo in both absolute and percentage improvement. There was noticeable reduction in plaque compared to a placebo.

Example 3

[0095] A clinical study comparing V-MI scores of subjects using the composition of Table showed a statistically significant difference between original V-MI scores and V-MI scores after three months of treatment with the composition, which indicates the composition is effective at calculus dissolution.

Example 4

[0096] In another clinical study, the composition of table 1 was shown to be effective at calculus inhibition.

Example 5

[0097] Another clinical study showed a reduction in gingivitis, plaque, and bleeding for those using the composition of table 1.

Example 6

[0098] 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, as described above, in the amounts shown. The composition was sealed in system **500**, illustrated in FIG. **5**.

TABLE 3

Ingredient	Supplier	Weight %	Exemplary Wt % Range
Purified Water	Copacker	91.604	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
Zinc Gluconate USP	American International	0.592	0.001-1.5
Cinnamon Bark (Oil)	Spectrum	0.250	0.001-2
Clove Bud (Oil)	Spectrum	0.005	0.001-2
Red #40 (1% sol.)	Pylam	0.099	0.000005-1

[0099] Another clinical study showed a reduction in gingivitis, plaque, and bleeding for those using the composition of table 3.

Example 7

[0100] Another clinical study showed a reduction in gingivitis, plaque, and bleeding for those using the composition of table 2.

Example 8

[0101] Another clinical study showed a reduction in calculus for those using the composition of table 4.

TABLE 4

Ingredient	Supplier	Weight %	Exemplary Wt % Range
Purified Water	Copacker	91.504	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	Dishman Pharmaceuticals	0.100	0.001-1
Zinc Gluconate USP	American International	1.184	0.001-1.5
Cinnamon Bark (Oil)	Spectrum	0.250	0.001-2
Clove Bud (Oil)	Spectrum	0.005	0.001-2
Red #40 (1% sol.)	Pylam	0.099	0.000005-1

[0102] The present invention has been described above with reference to various exemplary embodiments. However, those skilled in the art will recognize that changes and modifications may be made to the exemplary embodiments without departing from the scope of the present invention. For example, the various operational steps, as well as the components for carrying out the operational steps, may be implemented in alternate ways depending upon the particular application or in consideration of any number of cost functions associated with the operation of the system, e.g., various steps may be deleted, modified, or combined with other steps. These and other changes or modifications are intended to be included within the scope of the present invention, as set forth in the following claims.

1. A method to improve oral health comprising:

providing a system, including a composition within a container wherein the composition comprises a positively charged active to inhibit calculus buildup and an active ingredient for measurably improving oral health and wherein the container comprises a vial and an applicator portion;

accessing the composition; and

selectively applying the composition onto a surface within an oral cavity.

2. The method of claim 1, wherein the positively charge active includes zinc ions.

3. The method of claim 1, wherein the viscosity of the composition is greater than about 20,000 centipoise.

4. The method of claim 1, wherein the viscosity of the composition is about 25,000 to about 100,000 centipoise.

5. The method of claim 1, wherein the viscosity of the composition is about 30,000 to about 50,000 centipoise.

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

7. A method to improve oral health comprising, the method comprising the steps of:

providing a kit, including a plurality of systems, wherein each system includes a composition within a container and wherein the composition comprises a positively charged active ingredient for measurably improving oral health and has a viscosity greater than about 20,000 centipoise;

accessing the composition; and

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

8. The method of claim 7, wherein the positively charged active is configured to mitigate calculus buildup.

9. The method of claim 7, wherein the viscosity of the composition is about 25,000 to about 100,000 centipoise.

10. The method of claim 7, wherein the viscosity of the composition is about 30,000 to about 50,000 centipoise.

11. The method of claim 7, wherein said 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 composition comprises a plurality of positively charged active ingredients for measurably improving oral health.

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

providing a composition within a container, wherein the composition includes a plurality of positively charged active ingredients and is configured to maintain contact with a surface for an extended period of time; and

selectively applying the composition to a surface within an oral cavity before an extended period of rest.

14. The method of claim 13, wherein one of the plurality of positively charged active ingredients includes a broad-spectrum antimicrobial agent.

15. The method of claim 13, wherein the step of selectively applying occurs prior to a period of reduced saliva production.

16. The method of claim 13, wherein the step of selectively applying occurs prior to a period of reduced eating and talking.

17. The method of claim 13, wherein one of the plurality of active ingredients comprises a material selected from the group consisting of cetylpyridinium chloride, dicalcium phosphate dehydrate, hydrogen peroxide, sanguinaria extract, sodium bicarbonate, sodium lauryl sulfate, stannous fluride, 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, poloxamer, and stannous pyrophosphate.

18. The method of claim 13, wherein the step of providing a composition within a container comprises providing a container including a removable cap and a removable spout.

19. The method of claim 13, wherein the step of providing a composition within a container comprises providing a composition including about 0.001 weight percent to about 1 weight percent cetylpyridinium chloride and about 0.001 weight percent to about 2 weight percent zinc gluconate.

20. The method of claim 13, wherein the step of providing a composition within a container comprises providing a composition including an agent to facilitate maintaining at least one of the plurality of positively charged active ingredients in its positively charged state.

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