Antiseptic Mouth Rinses: An Update on Comparative Effectiveness, Risks and Recommendations

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Abstract

Purpose: Antiseptic mouth rinses are widely recommended and marketed to improve oral health. This article summarizes current studies on the comparative effectiveness of selected antiseptic mouth rinses in controlling plaque and gingivitis, as well as risks associated with daily exposure, including salivary flow rate, oral cancer and wear of composite restorations.

Methods: Electronic database searches were conducted using Google Scholar and PubMed to identify articles comparing the effectiveness of 4 commercially marketed antiseptic mouth rinses differing in active ingredients (0.12% chlorhexidine gluconate, essential oils (menthol, thymol and eucalyptol) and methyl salicylate, 0.7% cetylpyridinium chloride and 20% aloe vera gel) for controlling plaque and gingivitis. Criteria for inclusion included controlled clinical trials and systematic reviews appearing in English language publications evaluating the
and methyl salicylate provide clinically significant anti–gingivitis and anti–plaque benefits. Cetylpyridinium chloride has been found to provide only limited clinical benefits compared to inactive control mouth rinse. Inadequate evidence is available to evaluate the clinical effectiveness of aloe vera gel. Chlorhexidine, essential oils and cetylpyridinium have been found to be safe. However, limited data are available on the effects of the mouth rinse on wear patterns of dental restorations. Studies reviewed reported no significant difference in salivary flow rate related to alcohol based mouth rinse.

**Conclusion:** Research supports the effectiveness of antiseptic mouth rinses in reducing plaque and gingivitis as an adjunct to home care. Insufficient evidence is available to support the claim that oral antiseptics can reduce the risk of developing periodontitis or the rate of progression of periodontitis.

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**Introduction**

Dental plaque is the primary etiology for chronic gingivitis, which typically develops within 10 to 21 days in the absence of plaque control. Approximately 50% of the population over the age of 30 has some form of gingivitis. A relatively high degree of motivation, manual dexterity and compliance in oral hygiene regime are required to achieve the level of oral hygiene necessary to control bacterial plaque formation. The hard tissues of the teeth are not the only surfaces that plaque will colonize. The oral mucosa and the specialized mucosa of the tongue constitute about 80% of the remaining oral surfaces colonized by plaque biofilm. These surfaces serve as reservoirs for pathogenic bacteria, which can re–colonize on the teeth.

Using an antiseptic mouth rinse to supplement mechanical plaque removal can produce an antimicrobial effect throughout the mouth. Chemical agents in a mouth rinse should be effective at modifying the microbiota by selectively eliminating pathogens without negatively impacting the normal flora that may result in an overgrowth of pathogenic organisms. Evidence shows that the long–term twice daily use of 0.12% chlorhexidine gluconate

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Since 1931 the ADA has been placing its “Seal of Acceptance” on oral homecare dentifrice and mouth rinse. To earn its seal, the ADA requires 2 positive clinical trials lasting 6 months in duration, with an intermediate evaluation at 3 months, evaluating the product's efficacy, safety of the chemical agents and patient compliance. Generally, agents or drugs must also receive approval by the FDA in order to be marketed in the U.S. The ADA evaluates the product itself, but the FDA evaluates the products' individual active ingredients to determine if they are recognized as safe, effective and not misbranded. All of the products included in this review have been approved by the FDA. Currently, formulation containing essential oils and methyl salicylate is the only mouth rinse that has earned the ADA seal of acceptance to be effective against plaque and gingivitis. Chlorhexidine products had previously earned the ADA seal of acceptance, but recent changes to the ADA seal program have phased out all prescription products.

Methods and Materials

The purpose of this systematic review was to address the following focused question: What is the effectiveness of commercial antiseptic mouth rinses in controlling plaque and gingivitis? A secondary focused question was: What are the risks associated with daily use of antiseptic mouth rinses? The latter question targeted the effects antiseptic mouth rinses have on salivary flow rate, oral cancer and wear of composite restorations. Electronic database searches were conducted using Google Scholar and Pub Med to identify articles published between 2007 and April 2011 that compared the effectiveness of 4 commercially–marketed antiseptic mouth rinses: chlorhexidine gluconate 0.12%, essential oils and methyl salicylate, cetylpyridinium chloride 0.7% (Crest Pro Health®; Proctor & Gamble, Cincinnati, Ohio) and 20% aloe vera gel (Natural Dentist® Healthy Gums Daily Oral Rinse®, Caldwell Consumer Health, LLC, Blue Bell, Pa) for controlling plaque and gingivitis. Table I provides an overview of the 4 antiseptic mouth rinse formulations reviewed. Criteria for inclusion included controlled clinical trials and systematic reviews appearing in English language publications providing data on comparative effectiveness in controlling plaque and gingivitis, as well as risks, including salivary flow rate, oral cancer and wear of composite restorations. Selected studies reference list were screened for additional papers. Table II provides a list of key words used in the search strategy. Eligibility criteria included peer reviewed journals, controlled clinical trials, randomized controlled clinical trials and/or longitudinal studies. Abstracts were screened for relevancy to the focus question in order to be considered. Hundreds of articles were screened and 42 were chosen that met the inclusion criteria. Full text papers were reviewed independently by the authors for inclusion in the study.
the area of treatment, absorption to the available soft tissues and the subsequent slow release into the saliva. The longer the product's active ingredients remain in the oral cavity the greater the product's effectiveness.\(^6\)

Saliva is continually refreshed, rinsing away the active ingredients of mouth rinse. But plaque remaining after mechanical cleaning absorbs mouth rinse antimicrobials, serving as a reservoir to prolong the product's substantivity. Plaque most frequently remains in fissures, interproximal spaces and at the gingival margin where antimicrobial activity is needed most. This theory does not promote incomplete oral hygiene, but does reduce the negative effects of plaque left behind and reinforces the benefits of mouth rinse use in patients with poor plaque control.\(^7\)

Dental professionals should be recommending antiseptic mouth rinses that have extended substantivity, however, consideration for the patient's taste preference, history of alcoholism, religious beliefs and/or their severity of periodontal disease must be considered when making a recommendation. There are many studies comparing the effectiveness of 0.12\% chlorhexidine gluconate, essential oils and methyl salicylate, 0.7\% cetylpyridinium chloride and 20\% aloe vera gel in controlling plaque and gingivitis. Studies included used one active agent group that was compared against a placebo and/or vehicle control groups. The outcome for comparisons assessed test subjects for gingivitis by the plaque index (PI), gingival index (GI) and/or bleeding on probing (BOP). The results of these studies are reviewed below.

### Table I:

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<th>Popular OTC and RX Mouth Rinses</th>
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**Chlorhexidine Gluconate 0.12\% Mouth Rinse**

Chlorhexidine gluconate is the most effective antiseptic mouth rinse available today. Chlorhexidine tightly binds to tooth structure, oral tissues and dental plaque and releases slowly, resulting in 8 to 12 hour substantivity.\(^8\) Side effects, such as brown staining, calculus formation and temporary loss of taste, limit the long term use of this product.\(^9\) The mechanisms of action for this mouth rinse are rupturing of the bacterial cell membrane resulting in cell death and inhibiting pellicle formation and plaque colonization. Chlorhexidine has been shown to penetrate dental plaque biofilm killing pathogens. Due to the reduced effectiveness caused by positively charged dentifrice ingredients interacting with chlorhexidine, it is recommended to rinse 30 minutes after tooth brushing.\(^10\)

Chlorhexidine gluconate can be alcohol or non–alcohol based. The most commonly prescribed chlorhexidine product (Peridex®) contains alcohol. Chlorhexidine mouth rinse products are available by prescription only, which limits patient accessibility. Side effects are a concern and should be discussed with the patient before prescribing so that risk versus benefit can be evaluated. This product is typically recommended to patients with moderate to severe periodontal disease and alcoholics. Chlorhexidine can also be used in patients with severe periodontal disease and alcoholics. It is recommended to rinse 30 minutes after tooth brushing.
Seven studies were reviewed comparing the effectiveness of chlorhexidine, essential oils and aloe vera gel formulations.\textsuperscript{9,11–16} Of those, 4 found chlorhexidine to be superior to both essential oils and aloe vera gel,\textsuperscript{9,13,14,16} 2 found no significant difference between chlorhexidine and essential oils\textsuperscript{11,12} and 1 found no significant difference between chlorhexidine and aloe vera gel.\textsuperscript{15} In Gunsolley’s 2006 meta–analysis of 6 month randomized clinical trials, all 7 studies reviewed agreed that chlorhexidine was more effective in reducing plaque and gingival inflammation than mouth rinses containing essential oils.\textsuperscript{17} Although studies consistently find chlorhexidine gluconate provides the greatest anti–plaque and anti–gingivitis benefits available today, the negative side effects associated with long term use and limited availability (prescription only) may decrease patient compliance and/or the frequency of professional recommendation.\textsuperscript{11}

**Essential Oils and Methyl Salicylate Mouth Rinse**

Essential Oils refer to over the counter antiseptic mouth rinse containing 2 phenol related essential oils, thymol and eucalyptol mixed with menthol and methyl salicylate in a hydro–alcoholic vehicle. It is the antiseptic mouth rinse with the longest history, dating back to the nineteenth century. Most essential oils contain alcohol (as a solvent) at a concentration of approximately 22%, which is contraindicated for young children and patients who are immune–compromised, have mucositis, a history of alcohol abuse and/or undergoing radiation therapy for head and neck cancer.\textsuperscript{18}

The mechanisms of action for this antiseptic mouth rinse formulation are two–fold: rupturing of the bacterial cell membrane resulting in cell death and preventing bacterial aggregation and recolonization, thus decreasing plaque mass. It has been demonstrated that essential oils can penetrate dental plaque biofilm killing pathogens even in interproximal spaces.\textsuperscript{18} Because of its diffusion into the biofilm, essential oils have substantive activity extending several hours beyond the rinsing period. It is the only mouth rinse available today that is approved by the ADA for chemotherapeutic control of supragingival plaque and gingivitis.\textsuperscript{5}

**Table II:**

| List of Key Words Used in Search | View inline | Download powerpoint |

Ten studies were reviewed comparing the effectiveness of essential oils, chlorhexidine, cetylpyridinium and aloe vera gel formulations.\textsuperscript{3,11–16,19–21} Of these, 3 studies found chlorhexidine superior to both essential oils and aloe vera gel,\textsuperscript{13,14,16} 3 studies comparing essential oils and cetylpyridinium found no difference,\textsuperscript{3,19,21} 2 studies testing essential oils and chlorhexidine found no difference,\textsuperscript{11,12} 1 study found essential oils better than cetylpyridinium\textsuperscript{20} and 1 study found aloe vera gel superior to essential oils and chlorhexidine.\textsuperscript{15} In the 2006 meta–analysis, 20 studies reviewed claimed chlorhexidine to be 40% more effective in reducing plaque and gingival inflammation than mouth rinses containing essential oils.\textsuperscript{17} One author speculated that the burning sensation when using...
Cetylpyridinium Chloride 0.7% Mouth Rinse

Cetylpyridinium Chloride is a quaternary ammonium compound that has antiseptic properties. It is a broad spectrum antimicrobial agent which has proven effective for preventing supragingival plaque formation and reducing gingivitis. Similar to other antiseptic mouth rinses, cetylpyridinium ruptures the bacterial cell membrane, causing leakage of intracellular material and ultimately cell death. Cetylpyridinium has been shown to alter bacterial metabolism and growth. The chemical binds to both tooth structure and dental plaque biofilm producing substantive action for up to 6 hours after rinsing. Like chlorhexidine, cetylpyridinium rinse may be adversely affected by ingredients found in dentifrice. Rinsing with water prior to use or waiting 30 minutes after brushing is recommended. Side effects are similar to chlorhexidine, but less severe. Cetylpyridinium is cleared from the mouth more rapidly than chlorhexidine, which explains the lower efficacy for this compound.

Five studies were reviewed comparing the effectiveness of cetylpyridinium, chlorhexidine and essential oil formulations. Of these, 3 studies found no difference between essential oils and cetylpyridinium, 1 study favored essential oils over cetylpyridinium and 1 found both essential oils and chlorhexidine better than cetylpyridinium in reducing plaque and gingival inflammation. Seven studies reviewed in the 2006 meta–analysis showed inconsistent results because cetylpyridinium chloride concentrations varied between 4.5 to 7%. Although the 6 month results were promising for the non–alcohol–based product, more long–term studies are recommended to establish a greater level of evidence comparable to the evidence available for chlorhexidine and essential oils mouth rinse agents. To date, Crest Pro–Health® has not earned the ADA seal of approval.

Aloe Vera Gel 20% Mouth Rinse

Natural, organic and herbal products are gaining popularity among today's more educated consumers. Aloe vera gel antiseptic mouth rinses are appealing because they do not contain alcohol, artificial preservatives or artificial colors and flavors. Most herbal rinses claim only to kill bad breath germs. Although one manufacturer (Natural Dentist®) claims anti–plaque and anti–gingivitis effectiveness, there is limited research data supporting this claim.

Echinacea, goldenseal and grape fruit seed extract are 3 active ingredients in antiseptic aloe vera gel mouth rinse that exhibit anti–inflammatory and anti–fungal therapeutic effects. The mechanism of action for these herbal extracts is disruption of the bacterial membrane and release of the cytoplasmic contents, within 15 minutes after rinsing. Research by Kaim et al indicates antiseptic aloe vera gel mouth rinse significantly reduces salivary aerobic, microaerophilic and anaerobic bacteria for up to 2 hours. The exact substantivity is still unclear – more research is needed to determine this.

Four studies were reviewed comparing the effectiveness of aloe vera gel, chlorhexidine and essential oil.
number of participants. The larger of these, with 63 randomly assigned participants, found chlorhexidine to be significantly better than aloe vera gel. In the smaller study, 20 volunteers participated, with results favoring chlorhexidine as most effective, followed by aloe vera gel and essential oils, respectively, in reducing plaque and gingival inflammation. There is limited research available to support recommending aloe vera gel over other antiseptic mouth rinse to control gingival diseases.

A secondary focus question was: “What are the risks associated with daily use of antiseptic mouth rinses?” This question targeted the effects antiseptic mouth rinses has on salivary flow rate, oral cancer and wear of composite restorations. The results of the literature review are summarized below.

**Alcohol Containing Mouth Rinse and Salivary Flow Rate**

Many antiseptic mouth rinse products contain alcohol (ethanol) to keep flavoring agents and active ingredients in solution and biologically active. A number list alcohol as an active ingredient, claiming antiseptic and/or germicidal properties. In order to be considered an effective germicide, alcohol concentrations should range between 50 to 70%. Even the highest alcohol concentration available today (26.9%) is well below the level necessary for alcohol to be considered an effective antiseptic. Alcohol–based mouth rinse has been linked to desiccation of the oral mucosal membrane. Many dental care providers have a misconception that alcohol in mouth rinse negatively affects the flow rate of saliva and/or the salivary pH in patients that already have xerostomia.

Xerostomia is well–defined as a reduction or absence of saliva in the mouth, a subjective perception of dry mouth. Most often, xerostomia is a side effect of certain medications, radiation therapy for oral pharyngeal cancer and/or systemic diseases like diabetes and Sjogren's syndrome. With the recent increase in these compounding factors, dry mouth is a major concern for today's dental provider. Dental diseases such as caries, gingivitis and periodontitis are all exacerbated with low salivary flow. All 3 research studies reviewed that focused on the effects of salivary flow and alcohol–based mouth rinses reported no significant difference in salivary flow rate or salivary pH related to the use of alcohol based mouth rinse. Any perception of dry mouth immediately following rinsing is of short duration. Therefore, alcohol containing products can be recommended to most patients.

**Alcohol Containing Mouth Rinse and Oral Cancer**

Oral and oropharyngeal cancers are considered the sixth most common cancers in the world. According to the National Cancer Institute, “the age–adjusted incidence rate was 10.4 per 100,000 men and women per year," and “the age–adjusted death rate was 2.5 per 100,000 men and women per year" based on cases from 2003 to 2007. In the past 3 decades, 9 epidemiologic studies have been conducted on the relationship between alcohol use and oral cancer. We use cookies on this site to enhance your user experience. By clicking any link on this page you are giving your consent for us to set cookies.
Rinsing with an ACM is considered low alcohol exposure when used according to manufacturer directions: 0.5 fl oz of 25% alcohol twice daily for 30 seconds. This type of exposure is equivalent to the consumption of 1 to 2 alcoholic beverages per day, which would most likely not increase the risk for oral cancer. Mouth rinse use is known to be higher among drinkers and smokers. It is difficult to eliminate the confounding effects of these variables in research studies. The mechanism by which alcoholic beverages may induce human oral cancer is related to the ingestion, topical exposure and/or solvent action that enhances absorption of tobacco and other carcinogens into the tissues.\textsuperscript{32}

The International Agency for Research on Cancer has identified the long term habitual consumption of alcoholic beverages can greatly increase the risk for oral cancers.\textsuperscript{33} Commercial mouth rinse contains pharmaceutical grade ethanol alcohol, which has not been found as a carcinogen. Alcoholic beverages contain chemicals and additives, such as urethane, which is a known carcinogen.\textsuperscript{34} Current evidence strongly suggests that ACM use does not increase the risk for oral cancer.\textsuperscript{27,30,32–35} Research must meet certain criteria to establish a causal relationship between ACM and oral cancer that would be acceptable to the scientific community. Shortcomings in study design are blamed for the failure of studies to date supporting a connection between oral cancer and alcohol containing mouth rinses.\textsuperscript{33}

**Mouth Rinse and Composite Restoration Wear**

Antiseptic mouth rinse active ingredients and/or low pH may affect the hardness, gloss, color and wear of composite restorations.\textsuperscript{36} Of the mouth rinses reviewed, chlorhexidine and aloe vera gel are less acidic (5 to 7 pH)\textsuperscript{26,37} than essential oils and cetylpyridinium (3.8 to 4.8 pH).\textsuperscript{37,38} During bacterial acid attacks, enamel subsurface dissolution occurs at this same pH range of 3.8 to 4.8.\textsuperscript{39} These facts suggest that essential oils and cetylpyridinium products could have a negative effect on restorations due to low pH, especially in patients who use these products excessively.

Five recent studies evaluating the effects of antiseptic mouth rinse on composite restorations found that mouth rinses containing alcohol have a greater effect than non alcohol formulations, deducing that alcohol may cause composite wear.\textsuperscript{36,37,40–42} Aesthetics have become a top priority for patients, evidenced by the popularity of bleaching procedures both in office and at home treatments. One study evaluating the effects of alcohol containing mouth rinse on composite resins that had been subjected to prior bleaching found that all tested rinses had a statistically significant negative effect on surface hardness, gloss and color of the restorations.\textsuperscript{41}

Variables that influence the effect of antiseptic mouth rinse on a composite restoration are: age of the restoration, material composition and surface roughness.\textsuperscript{37} With the aging population of America, it is important to consider the effects these products could have on our geriatric patients. Other negative effects may depend on in vivo...
Conclusion

Gingivitis and periodontitis are among the most prevalent infections afflicting humans, making it essential for dental professionals to include risk assessment and disease management in patients' treatment plans to insure a favorable outcome. Risk factors for periodontitis to be considered include pathogen burden (specific microbes), systemic factors (diabetes, HPV, medications, etc.) behavioral habits (tobacco use, home care, etc.) and local factors (tooth proximity, faulty restorations, etc.).

Although research supports the effectiveness of antiseptic mouth rinse as adjunctive therapy to reduce plaque and gingivitis, patients must be advised that these products have little effect on periodontitis. Studies have found that agents used in rinsing can only reach 21% of a 1 to 6 mm periodontal pocket. Therefore, recommending the use of anti-plaque and anti-gingivitis antiseptic mouth rinse can be considered only as an adjunct for helping our patients control gingival diseases.

Strong evidence exists supporting the effectiveness of daily antiseptic mouth rinse used as an adjunct to mechanical plaque control to reduce or control plaque and gingivitis. Chlorhexidine gluconate 0.12% is the most effective mouth rinse available today, but side effects should be considered. ADA approved essential oils and methyl salicylate are very effective in controlling gingival disease, with less side effects than chlorhexidine. Cetylpyridinium chloride 0.7% and 20% aloe vera gel do not test as well as chlorhexidine or essential oils, but may be an option for certain patients. Health professionals should continually review products and evaluate their effectiveness based on evidence before making a recommendation to their patients.

Footnotes

- Diane R. Osso, RDH, MS, is a full-time faculty member at the Community College of Denver Dental Hygiene Program. Nehal Kanani, RDH, BS, is a degree completion student at the University of Mayland's Department of Periodontics

- This study supports the NDHRA priority area, Health Promotion/Disease Prevention: Investigate the effectiveness of oral self-care behaviors that prevent or reduce oral diseases among all age, social and cultural groups.

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References


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