

Meta-analysis of the effect of an essential oil-containing mouthrinse on gingivitis and plaque

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Oral health is integral to the general health and well-being of patients.¹⁻⁵ Although largely preventable, oral disease is recognized to significantly burden the economic, psychological, and social development of communities across the globe.⁶ Gingivitis and other periodontal diseases continue to exist as serious challenges on a global scale. The Third National Health and Nutrition Examination Survey (NHANES) publication (NHANES III) reports gingivitis prevalence to be 86% of the adult US population,¹ whereas studies in Latin America report it to be as high as 100%⁷ and affecting over 95% of adults in Southeast Asia.⁸ In the United Kingdom, the Adult Dental Health Survey (2009) found that 54% of dentate adults had bleeding in the mouth, which is a sign of gingival inflammation.⁹

Treatment and prevention of gingivitis are important because, if left untreated, it can progress to more advanced periodontal disease.⁵ Recommendations on oral hygiene practices from dental practitioners have largely focused on the mechanical methods of daily oral hygiene, including toothbrushing and interdental cleaning as standards to achieving and maintaining good oral health.¹⁰ However, systematic reviews and meta-analyses have reported that mouthrinses can provide a benefit beyond mechanical oral hygiene alone in preventing plaque accumulation and gingivitis.^{3,10-12}

Published and unpublished evidence was collected by the sponsor (Johnson & Johnson Consumer Companies) from 32 long-term randomized clinical trials that totaled more than 5,000 healthy participants with gingivitis for whom an essential oil (EO)-containing

ABSTRACT

Background. Standard recommendations for oral hygiene practices have focused on mechanical methods (toothbrushing and interdental cleaning). Published evidence indicates antimicrobial mouthrinses provide oral health benefits beyond mechanical methods alone. The purpose of this meta-analysis was to evaluate the combined effectiveness of mechanical methods with essential oil-containing mouthrinses (MMEO) versus mechanical methods (MM) alone in achieving site-specific, healthy gingival tissue and reducing plaque and gingivitis.

Types of Studies Reviewed. All industry-sponsored clinical trials investigating the antigingivitis and antiplaque effects of essential oil (EO)-containing mouthrinses conducted from 1980 to 2012 were reviewed; 29 of 32 studies met the inclusion criteria of 6 months or longer duration, randomized, observer-masked, placebo-controlled, and with individual-level site-specific data. By-study treatment effects were estimated through generalized linear models for binary data and analysis of covariance for continuous data, and then combined using standard meta-analysis techniques; heterogeneity was also assessed.

Results. Summary odds ratios for a healthy gingival site and for a plaque-free site were, respectively, 5.0 (95% confidence interval [CI], 3.3-7.5) and 7.8 (95% CI, 5.4-11.2) for MMEO participants versus MM participants at 6 months. The summary percentage reductions in whole-mouth mean gingivitis and plaque at 6 months were 16.0 (95% CI, 11.3-20.7) and 27.7 (95% CI, 22.4-32.9), respectively. Responder analyses using aggregate individual-level data showed 44.8% of MMEO participants and 14.4% of MM participants achieved at least 50% healthy sites in their mouths at 6 months. Similarly, 36.9% of MMEO participants and 5.5% of MM participants achieved at least 50% plaque-free sites in their mouths at 6 months.

Conclusions and Practical Implications. This is the first meta-analysis to demonstrate the clinically significant, site-specific benefit of adjunctive EO treatment in people within a 6-month period (that is, between dental visits).

Key Words. Meta-analysis; antiplaque; antigingivitis; oral hygiene; mouthrinse; essential oils.

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antimicrobial mouthrinse (Listerine, Johnson & Johnson) was used.¹³⁻⁴¹ These studies were conducted for various reasons, including demonstrating efficacy of flavor variants, investigating modifications in formula excipients or process, examining efficacy and safety comparisons with marketed products, or evaluating oral hygiene regimens in comparison with mechanical methods.

All studies were designed to meet the commonly accepted professional and regulatory standards set by the American Dental Association (ADA) and the US Food and Drug Administration (FDA).^{42,43} The unpublished studies were not previously made available to the general public as peer review articles because some of them were implemented either to support regulatory submissions, applications for a seal of acceptance, or for internal knowledge. However, in the context of the recent movement of biomedical science toward increased data sharing, it is important that results from these long-term studies are disclosed to the scientific community, thereby contributing to evidence-based research in dentistry.

The purpose of this meta-analysis was to compare the degree of response to therapy (mechanical only versus mechanical with essential oil mouthrinse use) toward achieving gingival health. The primary objective was to compare the efficacy of combined mechanical oral hygiene and use of essential oils containing mouthrinses with that of mechanical oral hygiene (negative control) based on the percentage of healthy gingival sites identified at 6 months. A second objective was to examine treatment effects using other summary measures based on the plaque index (PI). Lastly, we evaluated and reported potential sources of heterogeneity of the treatment effect as related to differences among studies and study results.

METHODS

Individual study protocols were reviewed by each institutional review board committee at the time the individual study was conducted. This meta-analysis protocol was registered on PROSPERO (www.crd.york.ac.uk/PROSPERO, registration number: CRD42013006356), an

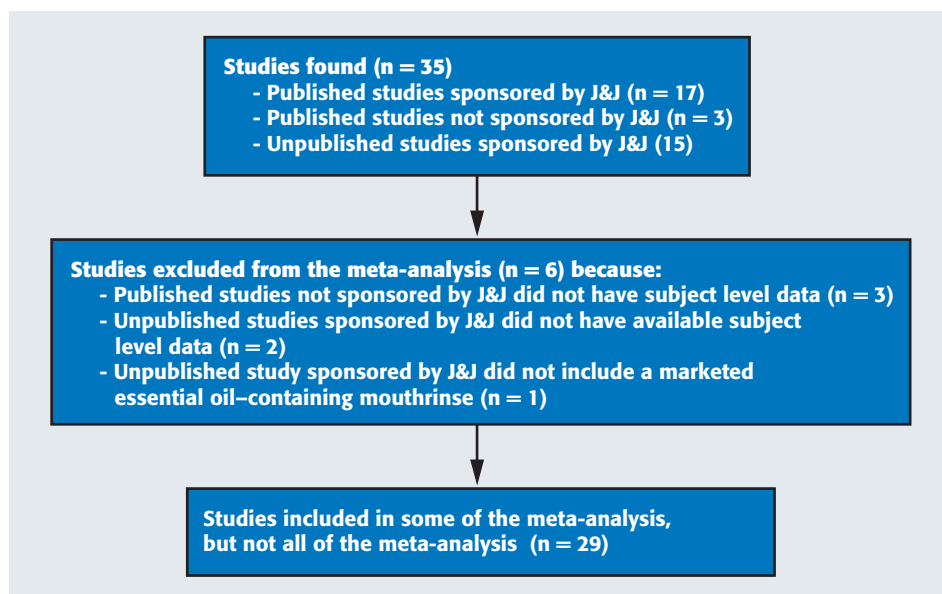


Figure 1. Study inclusion and exclusion criteria. J&J: Johnson & Johnson.

international prospective register of systematic reviews and meta-analyses.

Types of studies included. Thirty-two clinical studies, 6 months or longer duration, observer-masked, parallel, randomized, placebo-controlled, sponsored by Johnson & Johnson Consumer Companies and its predecessors that assessed the effect of marketed mouthrinses containing the fixed combination of 4 essential oils on gingivitis and plaque were considered for this meta-analysis. Twenty-nine studies met the inclusion criteria for this meta-analysis as individual-level data were required for both the site-specific measures in the meta-analysis and in the responder analysis. Twenty-nine studies were included in the gingivitis analyses, 27 of those studies were included in the analysis of the primary outcome variable, and 28 studies were included in the plaque analyses. It is not clear if other researchers of EO-containing mouthrinses have conducted 6-month clinical trials according to the ADA guidelines. Therefore, other trials of the intervention were not included, as not all published 6-month trials adhered to the ADA guidelines, utilized the modified gingival index (MGI), included a placebo control, and most importantly, had

ABBREVIATION KEY. ADA: American Dental Association. B/F: Brushing and flossing. DOF: Data on file. EO: Essential oil. FDA: Food and Drug Administration. GI: Gingival index. H: 5% Hydroalcohol control. J&J: Johnson & Johnson. MGI: Modified gingival index. MM: Mechanical methods alone. MMEO: Mechanical methods with essential oil-containing mouthrinses. N: No. NHANES: National Health and Nutrition Examination Survey. PI: Plaque index. SW: Sterile colored water control. Y: Yes.

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