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Comparative antiplaque and antigingivitis effectiveness of a chlorhexidine and an essential oil mouthrinse: 6-month clinical trial

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Abstract

Objectives: The objective of this study was to compare the antiplaque and antigingivitis effectiveness and the side-effect profiles of an essential oil-containing mouthrinse and a chlorhexidine-containing mouthrinse.

Material and Methods: One hundred and eight qualifying subjects, aged 20–57 years, were randomized into three groups: essential oil mouthrinse (Listerine® Antiseptic); 0.12% chlorhexidine mouthrinse (Peridex®); or 5% hydroalcohol negative control. At baseline, subjects received a complete oral soft tissue examination and scoring of the Loe–Silness gingival index (GI), Quigley–Hein plaque index (PI), Volpe–Manhold calculus index (CI), and Lobene extrinsic tooth stain index (SI). Following a complete dental prophylaxis, subjects started rinsing twice daily with their respective mouthrinse as an adjunct to their usual mechanical oral hygiene procedures. One of the rinses on each weekday was supervised. Subjects were reexamined at 3 and 6 months. The treatment groups were compared with respect to baseline demographic and clinical variables. The primary efficacy variables were GI and PI. Intergroup differences for all clinical variables were tested at 3 and 6 months using appropriate statistical procedures.

Results: All of the 108 randomized subjects were evaluable at 3 months, and 107 subjects were evaluable at 6 months. There were no statistically significant differences among the three groups at baseline, with the exception that the control group PI was significantly lower than that of the essential oil group ($p < 0.05$) and the chlorhexidine group ($p < 0.001$), and the essential oil mouthrinse group had a significantly greater number of subjects than the control group with body region SI scores $\geqslant 1.0$ ($p = 0.021$). At 6 months, the essential oil and chlorhexidine mouthrinses produced statistically significant ($p < 0.001$) GI reductions of 14.0% and 18.2%, respectively, and statistically significant ($p < 0.001$) PI reductions of 18.8% and 21.6%, respectively, compared with the control and were not statistically significantly different from each other with respect to plaque and gingivitis reduction. The chlorhexidine mouthrinse group had significantly more calculus and extrinsic tooth stain than either the essential oil mouthrinse group or the control group.

Conclusion: This 6-month controlled clinical study demonstrated that the essential oil mouthrinse and the chlorhexidine mouthrinse had comparable antiplaque and antigingivitis activity. Insofar as side effects associated with the chlorhexidine mouthrinse may limit patient compliance, it is suggested that each product can have a distinct role in the management of patients with periodontal diseases.

Key words: chlorhexidine; clinical trial; essential oils; gingivitis; listerine; peridex; plaque

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The incorporation of broad spectrum antimicrobial mouthrinses as adjuncts to patients' daily oral hygiene regimens has assumed greater importance with the recognition that most individuals are unable to consistently maintain adequate levels of plaque control using mechanical methods alone (Mandel 1988, Barnett 2003). The finding that a 0.2% chlorhexidine mouthrinse can effectively prevent plaque and gingivitis in the absence of other oral hygiene procedures using an experimental gingivitis study model (Loe & Schiott 1970) established the potential for antimicrobial mouthrinses in clinical practice. This led to a variety of subsequent studies, including studies of 6-month (Lang et al. 1982) and 2-year (Loe et al. 1976) durations primarily in Europe, and they demonstrated the antiplaque/antigingivitis effectiveness of chlorhexidine mouthrinses as adjuncts to usual oral hygiene methods. As a result, 0.2% chlorhexidine mouthrinses became widely used in many European countries. However, because of certain side effects associated with this agent, in particular tooth staining, calculus formation, and taste aberrations, it was deemed desirable to use lower levels of this agent, if possible. Thus, studies were conducted which demonstrated that 0.1% and 0.12% chlorhexidine mouthrinses had antiplaque and antigingivitis effectiveness comparable with that of a 0.2% chlorhexidine formulation (Lang et al. 1982, Segreto et al. 1986, Ernst et al. 1998). In addition, a 0.12% chlorhexidine mouthrinse (Peridex®, Zila Pharmaceuticals, Phoenix, AZ, USA) was shown in 6-month clinical trials to have significant antiplaque and antigingivitis activity (Grossman et al. 1986, Overholser et al. 1990). As a result of the accumulated literature and clinical experience, chlorhexidine mouthrinses have often been considered the benchmark for products of this type.

An essential oil-containing antiseptic mouthrinse (Listerine® Antiseptic, Pfizer Inc., Morris Plains, NJ, USA) has had an even longer history of clinical use. For example, in 1890, W. D. Miller wrote in *Microorganisms of the human mouth* that ''Listerine has proved to be a very useful and active antiseptic'' (cited in Mandel 1988), and in 1929, an independent assessment of this essential oil mouthrinse was published in the British journal, *The Lancet*, which showed it to have significant bactericidal activity against a variety of microorganisms and concluded it to be safe and effective (Reports and Analytical Records 1929). The active ingredient of this mouthrinse is a fixed combination of essential oils (0.064% thymol, 0.092% eucalyptol, 0.060% methyl salicylate, and 0.042% menthol). Early short-term controlled clinical studies demonstrated that the essential oil mouthrinse could also produce significant plaque and gingivitis reductions when tested in an experimental gingivitis model (Lusk et al. 1974, Fornell et al. 1975). A series of later longer-term studies, designed in accordance with guidelines to assess the antiplaque and antigingivitis effectiveness of chemotherapeutic products (Council on Dental Therapeutics 1986), confirmed the effectiveness of the essential oil mouthrinse when used as an adjunct to usual oral hygiene procedures over a 6-month period (Lamster et al. 1983, Gordon et al. 1985, DePaola et al. 1989, Overholser et al. 1990, Charles et al. 2002, Sharma et al. 2002, Bauroth et al. 2003, Sharma et al. 2004). These studies also showed that the essential oil mouthrinse did not promote either calculus formation or extrinsic tooth stain.

Given the extensive history and clinical testing of each of these rinses, a study was designed in accordance with the established guidelines (Council on Dental Therapeutics 1986) to directly investigate the comparative efficacy and side effect profiles of the 0.12% chlorhexidine and essential oil mouthrinses (Overholser et al. 1990). This study showed both mouthrinses to be significantly more effective than the negative control in reducing supragingival plaque and gingivitis. Although both mouthrinses had comparable antigingivitis effectiveness, the chlorhexidine mouthrinse was significantly more effective than the essential oil mouthrinse in reducing plaque. In addition, the chlorhexidine mouthrinse group had significantly more extrinsic tooth stain and calculus than either the essential oil or the control group.

The study reported herein was conducted to compare the antiplaque and antigingivitis effectiveness and the side effect profiles of the chlorhexidine and essential oil mouthrinses, and thereby determine the reproducibility of the previously reported study.

Material and Methods

This was a randomized, controlled, observer-blind, parallel-group 6-month clinical trial designed in accordance with American Dental Association Guidelines for Acceptance of Chemotherapeutic Products for the Control of Supragingival Dental Plaque and Gingivitis (Council on Dental Therapeutics 1986). All examinations were conducted by a single, experienced dental examiner. Reliability was established for the gingival index (GI) with a κ statistic of 0.75, which indicates satisfactory calibration (American Dental Association Council on Scientific Affairs 1997). One hundred and eight subjects, aged 20–57 years, who met the following inclusion criteria were entered into the study: a minimum of 20 sound, natural teeth; a mean plaque index (PI) (Turesky et al. 1970) of at least 1.95; a mean GI (Loe & Silness 1963) of at least 0.95. Teeth that were grossly carious, fully crowned or extensively restored, orthodontically banded, abutments, or third molars were not included in the tooth count. Subjects with gross oral pathology or who were taking antibiotic or antiinflammatory drugs were excluded. All subjects signed an informed consent form after the nature of the study was fully explained to them. The protocol was reviewed and approved by the Institutional Review Board of the Corning Besselaar Clinical Research Unit.

Qualifying subjects presented to the clinical site for baseline examinations having refrained from any oral hygiene procedures prior to their visit on that day. The baseline examinations consisted of the following:

- A complete intraoral soft-tissue examination was performed to document the condition of the oral mucosae at the outset of the study so that any changes in the course of the study could be identified and an assessment made as to whether these changes could be related to use of the test formulations.
- Extrinsic tooth stain was scored on the labial surfaces of the 12 anterior teeth using the Lobene extrinsic tooth stain index (SI) (Lobene 1968). The labial surfaces were divided into two regions, the gingival and body, each of which was scored for stain area and intensity on a scale of 0–3. The respective tooth area and intensity scores were multiplied by each other to obtain a tooth score; the tooth scores were

averaged to produce an individual subject mean score.

- Supragingival calculus on the lingual surfaces of the six mandibular anterior teeth was scored using the Volpe–Manhold calculus index (CI) (Manhold et al. 1965,Volpe et al. 1965, 1967, Barnett et al. 1989). The supragingival calculus in three defined planes on the lingual surface of each tooth was measured using a flat calibrated periodontal probe, the amounts were added, and a mean subject score was calculated.
- Gingivitis of the buccal and lingual marginal gingiva and interdental papillae of all scorable teeth was scored using the Loe–Silness GI (Loe & Silness 1963) in which the gingivae are scored on a four-point scale from 0 (absence of inflammation) to 3 (severe inflammation).
- Supragingival plaque was scored on the buccal and lingual surfaces of all scorable teeth using the Turesky modification of the Quigley–Hein PI (Turesky et al. 1970). Following disclosing with an erythrosine solution, plaque was scored on a six-point scale from 0 (no plaque) to 5 (plaque covers two-thirds or more of the tooth surface).

These examinations were all repeated at 3 and 6 months. On the days of the 3- and 6-month examinations, subjects refrained from oral hygiene procedures and the use of their assigned mouthrinse the morning of their examinations in order to eliminate possible bias resulting from residual product odor.

Following the baseline examination, each subject received a complete dental prophylaxis to remove all plaque, calculus, and extrinsic stain. Subjects were then assigned to either one of two test groups or a negative control group according to a computer-generated random code. Starting the day of the prophylaxis, subjects began rinsing with either 15 ml (chlorhexidine rinse) or 20 ml (essential oil rinse or 5% hydroalcohol negative control rinse) for 30 s, twice daily for 6 months. One of the daily rinses was supervised on each weekday. The rinsings were not done at the time of toothbrushing but at separate times. Subjects were provided with a supply of coded mouthrinse and plastic dosage measuring cups for their once-daily weekday and twice-daily weekend/holiday at-home rinsings. In addition, subjects maintained a diary to document these rinsings as well as their daily mechanical oral hygiene procedures. Soft nylon toothbrushes and fluoridated toothpaste were provided to all subjects and replenished periodically, as needed, for the duration of the study. Subjects returned their 16-oz mouthrinse bottles to the study supervisor monthly, at which time the residual volumes were measured as an indication of compliance. During the study, subjects followed their usual oral hygiene and dietary habits and were instructed to refrain from using commercial mouthrinses (other than their assigned study mouthrinses) and to advise the investigator if they initiated antibiotic or antiinflammatory drug therapy.

Statistical methods

The three groups were compared with respect to age and mean baseline GI and PI using an analysis of variance and Fisher's protected least significant difference test, with respect to gender and smoking status using a χ^2 contingency table analysis, and with respect to mean SI and CI using the Kruskal–Wallis and Wilcoxon's rank sum Tests. In addition, the groups were compared with respect to the number of subjects with an SI of at least 1.0 using a χ^2 contingency table analysis and Fisher's exact probability test.

This study was designed to provide a minimal power of 0.80 for detecting a statistically significant difference in plaque and gingivitis scores at the 0.05 probability level. The primary efficacy variables were whole-mouth mean GI and PI. For each of these variables, it was intended to analyze the 3- and 6-month data parametrically using an analysis of covariance, with the respective baseline values as the covariate, and Fisher's protected least significant difference test. However, the nature of the plaque data precluded this, and plaque was analyzed using an analysis of variance and Fisher's protected least significant difference test (see Results section). Stain and calculus were analyzed non-parametrically by the Kruskal–Wallis test and the Wilcoxon rank sum test. A χ^2 contingency table analysis and Fisher's exact probability tests were performed to evaluate differences in the number of subjects per group with an SI of 1.0 or greater.

Results

One hundred and eight subjects were entered study (34 in the essential oil group, 36 in the chlorhexidine group and 38 in the negative control group), 107 of which completed the full 6 months of the study. One subject in the control group left the study for personal reasons after the 3-month examination. Data for this subject are included in the 3-month analysis.

Baseline demographic information and means for clinical variables are shown in Table 1. There were no statistically significant differences among the treatment groups with respect to age, gender, smoking, or gingival, calculus, and SIs. The chlorhexidine and essential

Table 1. Baseline demographics and clinical means

Variable	Essential oil mouthrinse	Chlorhexidine mouthrinse	Negative control rinse
N	34	36	38
Age (years)			
mean (SD)	32.0 (6.6)	31.4 (9.4)	32.2 (6.3)
Gender			
#male (%)	12 (35.3)	13 (36.1)	14 (37.8)
#female (%)	22 (64.7)	23 (63.9)	23 (62.2)
#Smokers (%)	8 (23.5)	8 (22.2)	6 (16.2)
Gingival index*	1.31 (0.04)	1.35 (0.04)	1.27 (0.03)
Plaque index*	2.50 (0.07)	2.64 (0.07)	2.31 (0.04)†
Calculus index‡	0.30	0.26	0.17
Stain index			
gingival region‡	0.29	0.30	0.11
% $\geqslant$1.0	11.8	5.6	5.4
body region‡	0.49	0.22	0.05
% $\geqslant$1.0	14.7§	2.8	0.0

*Mean (SE).

†Significantly lower than the essential oil ($p<0.05$) and chlorhexidine ($p<0.001$) groups.

‡Mean.

§Significantly higher than control group ($p=0.02$).

oil mouthrinse groups had significantly higher PIs ($p<0.001$ and $p<0.05$, respectively) than the negative control group; there was no significant difference ($p=0.14$) between the PI of the two active mouthrinse groups. The essential oil mouthrinse group had a significantly greater number of subjects with body region SI scores of 1.0 or greater than the control group ($p=0.02$). Insofar as all subjects received a dental prophylaxis at the start of the study, the presentation of results is based on the assumption that all groups were equal with respect to plaque, calculus, and stain when treatment started, irrespective of their status when they were entered into the study.

Gingivitis

The mean baseline GI scores and mean 3- and 6-month adjusted GI scores are shown in Table 2. Analysis of covariance, using baseline scores as covariates, and Fisher's protected least significant difference test showed that the essential oil mouthrinse had no demonstrable effect on gingivitis at 3 months compared with control, but produced a statistically significant 14.0% reduction in gingivitis ($p<0.001$) at 6 months. Compared with control, the chlorhexidine mouthrinse produced significant gingivitis reductions ($p<0.001$) of 11.9% and 18.2% at 3 and 6 months, respectively. Although the chlorhexidine mouthrinse was significantly more effective than the essential oil mouthrinse at 3 months ($p<0.001$), there was no significant difference in gingivitis reduction between these two mouthrinse groups ($p=0.22$) at 6 months. Table 2a presents the mean GI differences at 3 and 6 months including the confidence intervals.

Plaque

The mean PI scores at baseline and at 3 and 6 months are presented in Table 3. As noted above, the chlorhexidine and essential oil mouthrinse groups both had significantly higher mean baseline PI scores ($p<0.001$ and $p<0.05$, respectively) than the control group, but were not significantly different ($p=0.13$). Heterogeneity of slopes precluded the use of an analysis of covariance for PI data. ANOVA and Fisher's protected least significant difference test showed that at 3 months, the chlorhexidine mouthrinse was significantly more effective in inhibiting plaque accumulation than either the negative control ($p<0.001$) or the essential oil mouthrinse ($p<0.05$). The essential oil mouthrinse was not significantly different from the control at 3 months. However, at 6 months, the chlorhexidine mouthrinse and the essential oil mouthrinse were both significantly more effective ($p<0.001$) than the control, producing plaque reductions of 21.6% and 18.8%, respectively. The chlorhexidine and essential oil mouthrinse groups were not significantly different from each other ($p=0.60$) with respect to plaque reduction at 6 months. Table 3a presents the mean PI differences at 3 and 6 months including the confidence intervals.

Calculus

Mean supragingival CI scores are presented in Table 4. Differences among treatment groups were assessed by the Kruskal–Wallis test. When overall significance was found, pairwise comparisons of treatment groups were assessed by the Wilcoxon rank sum test. At 3 months, the chlorhexidine mouthrinse group had significantly more calculus than both the essential oil mouthrinse

Table 2. Mean gingival index scores (SE)

Group	N	Baseline	3 months*	6 months*
essential oil	34	1.31 (0.04)	1.22 (0.03)	1.04 (0.03)†
chlorhexidine	36	1.35 (0.04)	1.04 (0.03)†,‡	0.99 (0.03)†
control	38§	1.27 (0.03)	1.18 (0.03)	1.21 (0.03)

*Adjusted means.
†Significantly different from control, $p<0.001$.
‡Significantly different from essential oil, $p<0.001$.
§$N=37$ at 6 months.

Table 2a. Mean gingivitis index score difference (95% confidence interval)

Contrast	Mean difference (95% confidence interval)		
	Baseline	3 months	6 months
essential oil versus control	0.04 (−0.06, 0.13)	0.04 (−0.03, 0.12)	−0.17 (−0.26, −0.08)
chlorhexidine versus control	0.07 (−0.02, 0.17)	−0.14 (−0.22, −0.07)	−0.23 (−0.32, −0.14)

Table 3. Mean plaque index scores (SE)

Group	*N*	Baseline	3 months	6 months
essential oil	34	2.50 (0.07)	2.02 (0.05)	1.77 (0.07)‡
chlorhexidine	36	2.64 (0.07)	1.79 (0.07)‡,§	1.71 (0.08)‡
control	38*	2.32 (0.05)†	2.12 (0.06)	2.18 (0.07)

*$N=37$ at 6 months.
†Significantly lower than the essential oil ($p<0.05$) and chlorhexidine ($p<0.001$) groups.
‡Significantly different from control, $p<0.001$.
§Significantly different from essential oil, $p<0.05$.

Table 3a. Mean plaque index score difference (95% confidence interval)

Contrast	Mean difference (95% confidence interval)		
	Baseline	3 months	6 months
essential oil versus control	0.18 (0.00+, 0.36)	−0.11 (−0.28, 0.07)	−0.41 (−0.62, −0.21)
chlorhexidine versus control	0.32 (0.14, 0.49)	−0.33 (−0.50, −0.16)	−0.47 (−0.67, −0.26)

+, lower limit = 0.0047.

Table 4. Mean calculus index scores

Group	*N*	Baseline	3 months	6 months
essential oil	34	0.30	0.21[†]	0.24
chlorhexidine	36	0.26	0.37[‡,§]	0.45[‡,¶]
control	38[*]	0.17	0.11	0.21

[*]$N = 37$ at 6 months.
[†]Significantly different from control, $p < 0.05$.
[‡]Significantly different from control, $p < 0.001$.
[§]Significantly different from essential oil, $p < 0.05$.
[¶]Significantly different from essential oil, $p < 0.001$.

Table 5. Mean stain index scores: gingival region

Group	*N*	Baseline	3 months	6 months
essential oil	34	0.29	0.13[†]	0.33[§]
chlorhexidine	36	0.30	1.61[‡,¶]	2.08[‡,¶]
control	38[*]	0.11	0.01	0.01

[*]$N = 37$ at 6 months.
[†]Significantly different from control, $p < 0.05$.
[‡]Significantly different from control, $p < 0.001$.
[§]Significantly different from control, $p < 0.01$.
[¶]Significantly different from essential oil, $p < 0.001$.

Table 6. % of subjects with mean stain index of 1.0 or greater (gingival region)

Group	Baseline	3 months	6 months
essential oil	11.8	5.9[*]	11.8[*,†]
chlorhexidine	5.6	50.0[*,†]	52.8[*,†]
control	5.4	0.0	0.0

[*]Significantly different from each other at 3 and 6 months, $p < 0.05$.
[†]Significantly different from control, $p < 0.05$.

Table 7. % Bleeding sites/roup

Group	Baseline	3 months	6 months
essential oil	33.29 (1068)[*]	24.10 (773)	12.72 (408)
chlorhexidine	35.60 (1248)	12.92 (453)	11.01 (386)
control	29.88 (1114)	19.52 (747)	20.65 (770)

[*]Percentage (# of sites).

group ($p < 0.05$) and the control group ($p < 0.001$), while the essential oil mouthrinse group had significantly more calculus than the control group ($p < 0.05$). At 6 months, there was no significant difference between the essential oil mouthrinse and the control group ($p = 0.92$); however, the chlorhexidine mouthrinse group had significantly more calculus than both of the other groups ($p < 0.001$). In addition, moderate-to-heavy calculus deposits were observed on the posterior teeth of eight subjects in the chlorhexidine mouthrinse group.

Extrinsic tooth stain

Mean gingival region SI scores are presented in Table 5. Differences among treatment groups were assessed by the Kruskal–Wallis test. When overall significance was found, pairwise comparisons of treatment groups were assessed by the Wilcoxon rank sum test. At 3 and 6 months, there was significantly more gingival region stain in the essential oil group ($p < 0.05$) and the chlorhexidine group ($p < 0.001$) compared with the control group; at both examinations, the level of stain in the chlorhexidine group was significantly greater ($p < 0.001$) than that in the essential oil group.

The percentage of subjects in each group having a mean gingival region SI score of 1.0 or greater is shown in Table 6. Frequency tables of subjects in each category were assessed by χ^2 contingency table analyses, with pairwise comparisons analyzed by Fisher's exact probability tests. At 3 months, 50.0% of subjects in the chlorhexidine group and 5.9% of subjects in the essential oil group had scores of 1.0 or greater; the corresponding percentages at 6 months were 52.8 and 11.8. With the exception of the pairwise comparison between the essential oil mouthrinse and control groups at 3 months, all the pairwise comparisons at 3 and 6 months (i.e., chlorhexidine versus essential oil, chlorhexidine versus control, and essential oil versus control) revealed statistically significant differences ($p < 0.05$). Results for body region extrinsic stain were similar to those for the gingival region (data not shown).

Gingival bleeding

The percentage of bleeding sites in each group was calculated from a transition table of GI scores in which sites were dichotomously distributed into bleeding (GI score of 2 or 3) and non-bleeding (GI score of 0 or 1) categories. The results are presented in Table 7. There was a considerable reduction in percent bleeding sites in the chlorhexidine and essential oil mouthrinse groups at 6 months, compared with both control and baseline. The bleeding site observations paralleled the significant GI reductions seen in these groups.

Soft tissue

During the course of the study, no oral mucosal lesions that could be attributed to any of the test mouthrinses were observed.

Discussion

This controlled comparative clinical trial demonstrated that the essential oil mouthrinse and the chlorhexidine mouthrinse produced significant reductions in supragingival plaque and gingivitis when used as adjuncts to subjects' usual mechanical oral hygiene

procedures. These findings add to the body of data supporting the effectiveness of these two antiplaque/antigingivitis products. The finding that the respective 6-month plaque and gingivitis reductions were not statistically significantly different from each other indicates that the two active mouthrinses had comparable clinical effectiveness. The gingivitis results are consistent with the results of a previously conducted 6-month comparative study (Overholser et al. 1990). However, in the previous study, while the two mouthrinses had comparable antigingivitis effectiveness, the chlorhexidine mouthrinse was statistically significantly more effective than the essential oil mouthrinse in reducing supragingival plaque. The plaque results in the current study may be illustrative of the variation than can occur among clinical trials.

The finding that levels of calculus deposition and extrinsic tooth stain were significantly higher in the chlorhexidine group than in the essential oil mouthrinse group is consistent with results of a previously reported study (Overholser et al. 1990). The occurrence of extrinsic stain and calculus deposition are recognized side effects of chlorhexidine mouthrinses (Grossman et al. 1986, Association Report 1988) and may limit patient compliance with long-term use. Therefore, it is likely that the chlorhexidine mouthrinse could have a greater role in situations when short-term plaque control is critical and usual mechanical oral hygiene procedures are difficult, e.g., in the immediate post-operative period after periodontal surgery, and the essential oil mouthrinse could have a role in the longer-term control of plaque and gingivitis during the maintenance phase of therapy. This may be especially important insofar as interactions between chlorhexidine and sodium lauryl sulfate, a commonly used dentifrice ingredient, have been demonstrated in vivo (Barkvoll et al. 1989), which result in an interference with chlorhexidine activity.

In summary, this 6-month controlled comparative clinical trial demonstrated that the essential oil mouthrinse and the chlorhexidine mouthrinse had comparable antiplaque and antigingivitis activity, with the chlorhexidine mouthrinse producing significantly higher levels of extrinsic stain and calculus. It is suggested that each of these products may have a distinct and useful place in the management of periodontal patients.

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