Evaluation of a stabilized chlorine dioxide paste-rinse combination regimen vs. a phenol-related rinse regimen.

Steven J. Spindler, D.D.S.* and Gregg A. Spindler**

The relative clinical efficacy was compared between a stabilized chlorine dioxide paste-rinse combination (test) regimen and a phenolic based rinse regimen (control) in a blind, crossover study. Twenty Class II or III periodontal patients were randomly assigned as test or control subjects. Parameter measurements of plaque score, gingival bleeding, gingival inflammation and pocket depth were recorded from the subjects at 0, 30 and 60 days following prophylaxis. The test group demonstrated significant improvements with all measured parameters except pocket depth when compared with controls. The mean bleeding scores in the test and control group were 0.727 and 0.750 respectively. At 60 days, the mean bleeding score was reduced to .427 in the control group and was 0.105 in the test group. The mean gingival index scores were reduced from 1.105 and 0.911 at baseline in the test and the control group to 0.561 and 0.733 respectively at 60 days. The mean plaque scores were reduced from 1.344 to .766 in the test group as compared to 1.327 to 1.055 in the control group. Probing depths were only slightly affected with means of 3.369 and 3.411 in the test and control groups which decreased to 2.950 and 3.144 respectively. The results suggest that the stabilized chlorine dioxide paste-rinse combination may have a greater efficacy than the phenol related rinse regimen in improving three of four periodontal parameters measured over 60 days.

Key Words: Halitosis, periodontal disease, gingival inflammation, volatile sulfur compounds.

Periodontal researchers for years have sought an ideal plaque control agent. Ideally, the agent should be efficacious in reducing disease activity and have breath freshening properties which enhance usage compliance.

In the last 15 years, only two compounds, chlorhexidine and triclosan, have been approved by The United States Food and Drug Administration for plaque and gingivitis. Both compounds have been studied extensively and have been shown to be efficacious for reducing plaque and gingivitis. (1, 2, 3, 4, 5, 6) Two chlorhexidine preparations have been accepted by The American Dental Association for plaque and gingivitis. A phenol related rinse formulation has also received acceptance from The American Dental Association for plaque and gingivitis, is widely commercially available and does not require a prescription. (7, 8, 9, 10, 11, 12) These compounds have also been used for the control of halitosis. (13)

*Private Practice, Limited to Periodontics, Metairie, Louisiana.
**SGS Statistical Consulting Services, Tucson, Arizona.
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Volatile sulphur compounds released by gram negative anaerobic bacteria from within the periodontal pocket (14, 15, 16, 17) and the dorsum of the tongue (13) have been isolated as principle odorants. Tonzetich (18), using gas chromatography, isolated hydrogen sulfide, methyl mercaptan and dimethyl sulfide in multiple mouth air samples from halitosis patients. Yaegaki, et al., (19) reported that volatile sulphur compounds were significantly elevated in periodontitis patients.

Although widely used for halitosis, the efficacy of stabilized chlorine dioxide has not been extensively reported in controlled studies. Numerous anecdotal reports using halimeters have shown reductions in measurable volatile sulphur compounds. Chemically, stabilized chlorine dioxide oxidizes both hydrogen sulfide and methyl mercaptan via an oxidation-reduction reaction. Therefore, in theory, because these compounds have been chemically reduced, halitosis improved by a quantitative reduction of organoleptic agents.

There have been isolated reports in the literature of improved periodontal parameters in gingivitis and periodontitis patients using stabilized chlorine dioxide for the control of halitosis. Chapek, et al., (20) reported that 67.42% of pockets in periodontal maintenance patients measuring 4 mm or more had a measurable depth reduction at the next recare appointment. The same group reported approximately a 72% reduction of bleeding upon probing in 239 refractory, bleeding pockets from one recare appointment to the next.(21) Goultschin (22) showed a 34.50% reduction in plaque scores when using a stabilized form of chlorine dioxide as compared with controls when all other forms of oral hygiene were suspended.

The purpose of this study was to investigate the relative efficacy on plaque level, gingival index, bleeding upon probing and pocket depth of a stabilized chlorine dioxide toothpaste and rinse regimen (a) as compared to a widely commercially available, phenol related rinse regimen (b).

a. Oxyfresh Toothpaste and Rinse, Oxyfresh Worldwide Inc., Spokane, WA.
Materials and Methods

20 patients were randomly assigned into two groups as "test", using the stabilized chlorine dioxide regimen, or "control" using the phenol related regimen. The patients were all Class II or III periodontal patients with 4 to 6 mm sites in a maintenance program. All patients had been previously treated for periodontitis.

Exclusion criteria for participation in the study included the following:
1. Significant cardiac histories, especially at risk for endocarditis,
2. Joint prosthesis requiring antibiotic premedication,
3. Active cancer therapy,
4. Compromised renal function,
5. Infectious diseases (i.e., HIV, tuberculosis, URTI),
6. Systemic diseases – diabetes, hepatic, lupus, etc.,
7. Oral candidiasis,
8. Oral autoimmune/mucocutaneous diseases,
9. History of dilantin, cyclosporin, calcium channel blockers in past 12 months,
10. Systemic antibiotics within last 3 months,
11. NSAIDS within last 3 months,
12. Chlorhexidine or sanguinaria based products in last 3 months.

Measurements
Site selection — All parameter sampling was done using the “Ramjford” 6 teeth, which included the maxillary right first molar, the maxillary right central incisor, the maxillary left first bicuspid, the mandibular left first molar, the mandibular left central incisor and the mandibular right first bicuspid. When a particular tooth was unavailable, an adjacent tooth was selected. Six sites per tooth were measured. All measurements were taken by a blind periodontist.

Baseline (day 0) — The parameter measurements taken were the Plaque Index (PLK 0-3), the Gingival Index (GI 0-3), bleeding upon probing (BOP 0-3) and pocket depth (PD). All patients received standard supportive periodontal maintenance procedures which included supragingival scaling and prophylaxis. All were instructed how to use the products and were given written instructions with the products. These instructions were the same for both groups except for the duration of the rinsing in the test group. The manufacturer recommends rinsing for 90 seconds. The controls were advised to rinse for at least 30 sec. with the phenolic related rinse. The subjects were instructed to use the respective products exclusively for the duration of the study, to do so twice each day and to record their compliance on a reporting form. The same measurements were repeated at 30 days and at 60 days. All patients were re-examined by the same periodontist who was blinded as to which products the patient was using. All four parameters were re-examined. Patients were re-screened for exclusion criteria.

Data Analysis — The data were grouped by measurement type and subjected to analysis of variance (ANOVA) for differences between the groups using a commercially available statistical computer package (c).

c. SAS, SAS Institute, Cary, NC.
Results

All patients completed the duration of the study. Compliance with the prescribed oral hygiene regimen was reported by each participant and measured as a percent. The compliance of the test group was 99.2% and was 99.1% in the control group.

The results for each parameter are shown in Table 1.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>0 days</th>
<th>std dev.</th>
<th>30 days</th>
<th>std dev.</th>
<th>60 days</th>
<th>std dev.</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIk control</td>
<td>1.327</td>
<td>0.774</td>
<td>0.811</td>
<td>0.698</td>
<td>1.055</td>
<td>0.744</td>
</tr>
<tr>
<td>PIk test</td>
<td>1.344</td>
<td>0.833</td>
<td>1.060</td>
<td>0.725</td>
<td>0.766</td>
<td>0.668</td>
</tr>
<tr>
<td>PD control</td>
<td>3.411</td>
<td>0.994</td>
<td>3.322</td>
<td>0.953</td>
<td>3.144</td>
<td>0.825</td>
</tr>
<tr>
<td>PD test</td>
<td>3.369</td>
<td>1.071</td>
<td>3.116</td>
<td>1.035</td>
<td>2.950</td>
<td>1.051</td>
</tr>
<tr>
<td>GI control</td>
<td>0.911</td>
<td>0.733</td>
<td>0.739</td>
<td>0.662</td>
<td>0.733</td>
<td>0.713</td>
</tr>
<tr>
<td>GI test</td>
<td>1.105</td>
<td>0.867</td>
<td>0.861</td>
<td>0.822</td>
<td>0.561</td>
<td>0.717</td>
</tr>
<tr>
<td>BOP control</td>
<td>0.750</td>
<td>0.789</td>
<td>0.350</td>
<td>0.628</td>
<td>0.427</td>
<td>0.615</td>
</tr>
<tr>
<td>BOP test</td>
<td>0.727</td>
<td>0.781</td>
<td>0.233</td>
<td>0.559</td>
<td>0.105</td>
<td>0.387</td>
</tr>
</tbody>
</table>

The mean bleeding scores were similar in the test and control group at baseline and measured to be 0.727 and 0.750 respectively. At 60 days the mean bleeding score was reduced to .427 in the control group and was nearly eliminated as reflected by the score of 0.105 in the test group. These findings were significant as P<.001. See figure 1.

Similarly, the mean gingival index scores were reduced from 1.105 and 0.911 at baseline in the test and the control group to 0.561 and 0.733 respectively at 60 days. These findings were significant as P<.001. See figure 2.

Plaque Scores were reduced from 1.344 to 0.766 in the test group as compared to 1.327 to 1.055 in the control group as shown in figure 3. These findings were significant as P<.001.

Finally, probing depths were only slightly affected with means of 3.369 and 3.411 in the test and control groups which decreased to 2.950 and 3.144 respectively. These findings were significant as P<.001. See figure 4.
In each pair, the bar on the left is the Control, the bar on the right is the Test.
**Discussion**

The stabilized chlorine dioxide referred to in this article is, chemically speaking, sodium chlorite (NaClO₂). Based upon common usage over the years, stabilized chlorine dioxide is a justifiable synonym for sodium chlorite.

The results of this study clearly demonstrate the efficacy of both paste-rinse protocols. The use of both products resulted in significant reductions in the plaque score, bleeding upon probing and the gingival index.

Very limited changes were noted with respect to probing depths. The lack of significance was expected as clinicians rarely note probing depth reductions due to the use of topically applied antiplaque agents.

The results of this study compare favorably with the work of other reports, particularly with respect to reports addressing the efficacy of phenolic-based rinses. Previous reports have demonstrated plaque reductions varying from 20 to 34% as compared with 20.5% in this study. Gingivitis reductions have been reported in the same range as compared to 19.5% in this study. (17, 18, 19)

The use of the phenolic regimen was included as a positive control in the crossover study design. The phenolic control was used since it is available as both a toothpaste and a rinse in The United States, unlike chlorhexidine. Since the test product performed better than the positive control, a relative efficacy can be established using the dual paste-rinse regimen. The efficacy of stabilized chlorine dioxide has not been previously reported as compared to placebos or other positive controls.

The duration of exposure to the active ingredients significantly differed between the test and control groups. In the test group, each subject was exposed to stabilized chlorine dioxide for approximately 120 seconds during brushings and 90 seconds during rinsing two times per day. In the control group, the subjects were only exposed to the phenol-related essential oils for 30 seconds twice each day. The duration of exposure to the active ingredients may have a significant affect on the improvements seen, favoring the test group.

The results of this study are based upon normal home use of the products according to the manufacturers' instructions and coupled with specific instructions on proper tooth brushing, flossing and rinsing. Additional controlled studies should separate the paste from the rinse to determine if the sole use of either can generate clinical improvements. Also, controlled studies of stabilized chlorine dioxide alone, divorced from the benefits of tooth brushing and flossing would provide additional useful information.

In conclusion, both the stabilized chlorine dioxide toothpaste and rinse regimen and the phenol-related rinse regimen resulted in measurable clinical improvements with respect to gingival bleeding, gingival inflammation and plaque scores during the 60 day observation period. These findings suggest that there may be significant periodontal benefits in using a stabilized chlorine dioxide toothpaste and rinse regimen.
References


