Effects on gingivitis of daily rinsing with 1.5% H₂O₂


Abstract. The purpose of this study was to compare 2 groups of adolescents undergoing orthodontic treatment with fixed appliances to determine whether once daily use of a mouthrinse containing 1.5% H₂O₂ along with toothbrushing would be better than toothbrushing alone in maintaining their periodontal health. The 2 groups of subjects were selected non-randomly but were matched for age and sex. The control group (N = 34) used toothbrushing and a mint-flavored 0.05% NaF mouthrinse once daily, while the treatment group (N = 25) used toothbrushing and a once daily rinse with a preparation containing 0.05% NaF and 1.5% H₂O₂ (Orthoflur®). 2 calibrated clinical examiners made single-blind clinical assessments of the plaque index, gingival index, and bleeding tendency in 6 standard sites per subject. They also noted any generalized mucosal irritations or staining of the teeth or tongue. Assessments were made before appliances were placed (baseline) and 1, 3, 6, 9, 12 and 18 months after appliances were placed.

Results indicated that although there were no significant differences at baseline, the Orthoflur group had significantly fewer study sites with gingival index or bleeding tendency scores greater than 1 than the control group from the 1-month through the 18-month examinations (P < 0.01), and significantly fewer sites with plaque index greater than 1 and bleeding tendency scores of 2 or more from the 3-month through the 18-month examinations (P < 0.02 and 0.01, respectively). No generalized mucosal irritations or clinically significant staining of the tongue or teeth were noted in either group during the study.

Key words: hydrogen peroxide; gingivitis; orthodontic treatment.

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During the last 2 decades, many studies have documented the antibacterial effects of H₂O₂ (for review, see Miyasaki et al. (1986)). These effects appear to be related to the availability of oxygen, which is bactericidal to obligate anaerobes, organisms sensitive to oxygen. The topical application of H₂O₂ rinses has been reported to reduce plaque formation and gingivitis (Wennström & Lindhe 1979) and arrest acute ulcerative gingivitis (Wade & Mirza 1964). Unfortunately, no long-term studies have tested the effectiveness of H₂O₂ rinses. Some studies have shown that a paste made of H₂O₂ and NaHCO₃ can be effective for antimicrobial treatment of periodontal disease (Keyes et al. 1978a, b, Rosling et al. 1983), but other studies have not found this method to be effective (West & King 1983, Greenwell et al. 1983 and 1985, Cerra & Killoy 1982).

The purpose of this study was to determine whether toothbrushing in combination with once daily use of a mouthrinse containing 1.5% H₂O₂ would be more beneficial than toothbrushing alone for maintenance of periodontal health in a long-term study of adolescents undergoing fixed orthodontic treatment. Adolescent orthodontic patients were chosen for study since they often show ineffective plaque control and gingivitis because of the difficulty of removing plaque while fixed appliances are in place (for review, see Boyd (1983)).

Material and Methods

Study population

60 adolescent patients were selected for this study from among those scheduled to have fixed orthodontic treatment at the Orthodontic Clinic of the School of Dentistry, University of California, San Francisco. Informed consent to participate in the study was obtained from both patients and their parents. Patients with a history of rheumatic fever, congenital heart disease, blood dyscrasias or diabetes mellitus were not included. Patients were also excluded if they were diagnosed as having juvenile periodontitis according to the criteria of Kornman & Robertson (1985). In addition, none of the patients had used antibiotics during the 6 months prior to orthodontic treatment. The study population was divided into a control group (N = 34) and a treatment group (N = 26). The first 26 patients in the control group and the treatment group were paired for age and sex. The mean age of the control group was 13.5 with a range of 10.3 to 17.2 years, while the treatment group had a mean age of 13.2 with a range of 10.1 to 17.4 years. There were 23 female and 11 male patients in the control group, and 17 female and 9 male patients in the treatment group.

Preventive treatment

All study patients received instructions in toothbrushing in the horizontal scrub method (Zachrisson 1976) with an ADA-approved sodium fluoride dentifrice (Crest Toothpaste, Proctor and Gamble Co., Cincinnati, OH). The instructions were provided by the same...
plaque control therapist. The therapist also reinforced these instructions, using the Plaklite® disclosing system (Bristo-Meyers, Stamford, CT), at subsequent banding/bonding visits (2–3 sessions) and at each monthly orthodontic treatment visit for the 18-month study period. In addition, the control group was instructed to use 0.05% NaF mint-flavored mouthrinse (Flurigard®, Colgate-Hoyt, Norwood, MA) once a day, while the treatment group was instructed to use daily a rinse of similar color, mint flavoring and a 0.05% NaF but also containing 1.5% H₂O₂ (Orthoflur®, Colgate-Hoyt, Norwood, MA). All study patients were instructed to keep ½ ounce of the rinse in their mouth for one minute, then to expectorate but not rinse with water after using the rinse. These instructions were also reinforced at each monthly visit.

When baseline clinical assessments were completed, all subjects received a prophylaxis consisting of coronal tooth polishing. Patients were also requested to maintain their usual frequency of check-ups with their general dentist during orthodontic treatment.

Clinical examinations

All study sites were evaluated before appliances were placed, and again at 1, 3, 6, 9, 12, and 18 months after appliances were placed. The assessments used were the plaque index (Silness & Löe 1964), gingival index (Löe & Silness 1963) and bleeding tendency (Armitage et al. 1982). Any generalized mucosal irritation, or clinically significant staining of the teeth or tongue were noted at each of these examinations. Localized mucosal irritation associated with rough edges of fixed orthodontic appliances were not included in this category. In each patient, the study sites were six proximal-buccal line angles on the following teeth: right maxillary first molar, mesiobuccal line angle; right maxillary central incisor, distobuccal line angle; left maxillary central incisor, distobuccal line angle; right mandibular central incisor, distobuccal line angle; left mandibular canine, distobuccal line angle; left mandibular first molar, mesiobuccal line angle. If a study tooth was missing, the corresponding tooth on the contralateral side was examined. The clinical examiners had no knowledge of the group to which a subject belonged, and patients were cautioned by the plaque control therapist not to reveal their group identity to the examiner.

Orthodontic treatment

After the baseline clinical assessment, all study patients were treated with an edgewise appliance on both upper and lower dental arches. All teeth had direct bonded appliances placed except first molars, of which 78% were banded and the remaining 12% were direct-bonded. Extractions were carried out in at least one arch in 42 (70%) of the study patients.

Compliance

To assess compliance with the use of the rinses, at the monthly orthodontic treatment visit the plaque control therapist asked patients how many days per month they had not used the rinse as recommended. If a patient reported missing an average of 10 or more days per month for 9 or more months of the 18-month study, the patient was classified as non-compliant.

Statistical analysis

A two-way analysis of variance was performed for all tested variables for intragroup differences from baseline and intergroup differences at each observation. Statistical significance was set at a P value of less than 0.05. Two clinical examiners independently performed all assessments. These examiners were carefully calibrated before the study and at 6-month intervals for the duration of the study for both inter-examiner and intra-examiner reproducibility (minimum of 85% reproducibility). The Kappa statistic was used to quantify agreement beyond chance (Hunt 1986).

Results

Complete data were obtained for 32 control subjects and 24 Orthoflur subjects. 4 subjects withdrew from the study when they moved away from the area. No significant differences were found between the 2 groups for baseline clinical indices.

The percentage of sites with a plaque index greater than 1 (Fig. 1) indicated a gradual increase in plaque accumulation from baseline to 9 months for both groups. The Orthoflur group showed significantly less of an increase after 3 months than the control group (P < 0.01). Intragroup increases from baseline were significant for the control group (P < 0.01) but not for the Orthoflur group.

The % of sites with a gingival index greater than 1 (Fig. 2) showed a pattern similar to that for the plaque index, but the %s for the Orthoflur group were significantly lower (P < 0.01) at the 1-

![Fig. 1. Mean % of sites with a plaque index greater than 1 for the control group and the group using a 1.5% H₂O₂ rinse (Orthoflur®) over the 18-month study period. Bars show standard deviation. Asterisks mark significant differences between groups at the designated examination.](image-url)
Effects on gingivitis of $\text{H}_2\text{O}_2$

Discussion

The results of this study show that once daily use of a mouthrinse containing 1.5% $\text{H}_2\text{O}_2$, in combination with toothbrushing, is more effective in maintaining periodontal health in orthodontic patients over a long term than is toothbrushing without such a rinse. This study is in agreement with previous clinical trials that have found $\text{H}_2\text{O}_2$ rinses to have beneficial effects on periodontal status (Wade & Mirza 1964, Bergenholtz et al. 1969, Johansen et al. 1970, Wennström & Lindhe 1979, Gomes et al. 1984). However, these previous studies covered a much shorter term than the present 18-month longitudinal investigation. Thus the length of this study addresses the concern that the antimicrobial effect of $\text{H}_2\text{O}_2$ may be transitory, or that plaque microorganisms might become resistant to the antimicrobial effect of $\text{H}_2\text{O}_2$.

Significant intragroup increases from baseline in gingival inflammation and bleeding were seen for the control group but not for the Orthoflur group. Previous studies have established that gingival inflammation generally increases after fixed appliances are placed (Zachrisson & Alnaes 1973, Zachrisson 1976, Boyd 1983). We hypothesize that in this study the lack of increase in these scores in the Orthoflur group occurred because the 1.5% $\text{H}_2\text{O}_2$ rinse was preventing gingival inflammation that would have developed if this rinse had not been used.

![Gingival Index](image1)

![Bleeding Tendency](image2)
H$_2$O$_2$ rinses have been used for many years as antiplaque-antigingivitis agents (for review see Gold 1985). Recently, several reports have described the antimicrobial activity of H$_2$O$_2$ as bactericidal for known periodontal pathogenic bacteria such as Actinobacillus actinomycetemcomitans, Haemophilus arophilus, Eikenella corrodens and Capnocytophaga gingivalis (Miyasaka et al. 1984, 1985, 1986). In addition, Wennström & Lindhe (1979) reported that an H$_2$O$_2$ rinse prevented colonization of filaments, fusiforms, motile and curved rods and spirochetes in developing plaque. The results of the present study offer additional clinical evidence of this antimicrobial activity. H$_2$O$_2$ in other types of preparations, such as in gels (Shipman et al. 1971), in toothpastes (Rundegren et al. 1973), and mixed with NaHCO$_3$ in a paste (Kyes et al. 1978a, b, Rosling et al. 1983), has also shown effects on plaque and gingivitis. Because all subjects in this study used a rinse that contained 0.05% NaF, it is necessary to rule out any antimicrobial effects of the NaF component of the rinses used. Both Tinano et al. (1976) and Andres et al. (1974) have shown that 0.05% NaF rinses do not exhibit antimicrobial activity. However, NaF is effective in controlling decalcification in orthodontic patients (Zachrisson 1976, O'Reilly & Featherstone 1987). Thus another possible benefit of the H$_2$O$_2$ rinse used in this study is that 0.05% NaF can be incorporated into it in a stable formulation. Efforts to incorporate fluoride in a stable and effective preparation in other antiplaque-antigingivitis agents, such as chlorhexidine rinses and Listerine rinse, have not been successful.

6 standard interproximal sites were used as study sites in this clinical trial because previous studies have demonstrated that they are representative of the status of the entire mouth with approximately a 90% confidence level (Shick & Ash 1961, Jamison 1963, Ramford 1974, Gettinger et al. 1983). Distobuccal sites of canines were used instead of premolars because in many of the subjects the premolars had been extracted for orthodontic purposes. Previous studies (Schei et al. 1959) have established that distal proximal surfaces show recordings of periodontal destruction similar to those of the mesial surfaces. Buccal surfaces were not included because these surfaces show less periodontal inflammation than proximal sites (Anérud et al. 1979, Clerethoven et al. 1988) and are more likely to show toothbrush abrasion (Zachrisson 1976). Lingual surfaces were not used as study sites because they are susceptible to increased examiner error (Glavind & Løe 1967). The intra- and interexaminer percentage agreement for the clinical indices and the Kappa statistics for both clinical examiners correspond well with those reported by others (Hunt 1986, Fleiss & Chilton 1983).

In this study, both groups showed excellent compliance with use of the mouthrinses. This was most likely because the patients (as they reported subjectively to the plaque control therapist) liked the taste of these rinses and found them convenient to use. When data were reanalyzed without the non-compliant subjects, the statistical results were similar to those values obtained from analysis of all subjects. The compliance attained for use of the rinse in this study was also higher than that reported for other types of adjunctive chemical preparation when used daily by adolescent orthodontic patients, such as brush-on SnF$_2$ gels (Boyd et al. 1988) or oral irrigators containing antimicrobial agents (Boyd et al. 1982).

Although none of the patients using the H$_2$O$_2$ rinse in this study developed generalized mucosal irritation, recent reports have documented several adverse effects of topically applied H$_2$O$_2$, such as pathologic changes of preneoplastic lesions in hamsters (Weitzman et al. 1984 and 1986) and inhibition of collagen synthesis and glucose metabolism in bone in vitro (Ramp et al. 1987). In these studies, however, the concentration of H$_2$O$_2$ necessary to induce these cellular changes was 30%, far in excess of the 1.5% H$_2$O$_2$ used in the Orthoflur rinse. Generalized mucosal irritation from H$_2$O$_2$ also appears to be related to the duration of contact with H$_2$O$_2$; Martin et al. (1983) found that even a 1% H$_2$O$_2$ solution would cause epithelial damage if it remained in continuous contact for more than 8 h with keratinized oral epithelium of the dog. Rees & Orth (1986) reported two cases of generalized mucosal irritations resulting from use of a 3% H$_2$O$_2$ rinse 3 to 5 times daily. In the present study, the 1.5% H$_2$O$_2$ rinse was used only once daily for a 1 minute duration, which is in line with current pharmacologic recommendations for topical oral rinses containing H$_2$O$_2$ (Gilman et al. 1980), and patients were cautioned not to exceed this frequency.

The results of this study do not indicate conclusively that the 1.5% H$_2$O$_2$ rinse used once daily is the optimal therapeutic level of H$_2$O$_2$ or the optimal frequency of application. Additional studies testing rinses having different concentrations of H$_2$O$_2$ and used with different frequencies will be necessary to determine the optimal therapeutic dose. Also, currently used clinical indices may not be sensitive enough to detect beneficial effects of mild preparations such as those reported by others (Hunt 1986, Fleiss & Chilton 1983).
as 1.5% H$_2$O$_2$ in patients with less severe gingivitis than shown by the patients in this study.

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**Zusammenfassung**

Die Wirkung täglicher Mundspülung mit 1.5% H$_2$O$_2$ auf die Zahnfleischzündung

Im Rahmen dieser Studie wurde beabsichtigt, 2 erwachsene Probandengruppen mit festen kieferorthopädischen Apparaten miteinander zu vergleichen, um klarzustellen, ob Zähneputzen mit zusätzlichen, einmal taglichen kieferorthopadischen Apparaten miteinander zu vergleichen um klarzustellen, ob Zähneputzen mit zusätzlichen, einmal taglichen

**References**


pen wurden generalisierte Schleimhautirritationen oder klinisch signifikante Verfärbungen der Zunge oder der Zähne registriert.

Résumé

Effets d’un rinçage quotidien avec 1.5% H2O2 sur la gingivite

Le but de cette étude a été de comparer deux groupes d’adolescents suivant un traitement orthodontique fixe en déterminant si un rinçage quotidien avec 1.5% H2O2 en plus du brossage serait plus efficace à maintenir un pareodont sain qu’un brossage seul. Les deux groupes de patients n’ont pas été répartis au hasard mais suivant l’âge et le sexe. Le groupe contrôle (n = 34) associait le brossage au rinçage quotidien avec une solution de 0.05% NaF mentholé. Le groupe test (n = 25) combinait le brossage au rinçage quotidien avec une solution de 0.05% NaF et de 1.5% H2O2 (Orthoflur®). Deux examinateurs ont effectué les mesures cliniques en simple aveugle: indice de plaque, indice gingival et tendance au saignement au niveau de six sites standardisés par sujet. Ils ont également noté toute irritation des muqueuses ou toute coloration des dents ou de la langue. Les mesures ont été prises avant le traitement orthodontique (initial) et 1, 3, 6, 9, 12 et 18 mois après la pose des appareils. Aucune différence n’a été notée lors de l’examen initial. Le groupe test avait significativement moins de sites avec des scores > 1 de GI et de tendance au saignement que le groupe contrôle du premier mois au dernier (P < 0.01). Ils avaient également moins de sites avec PII > 1 et tendance au saignement ≥ 2 entre le 3ème et le 18ème mois d’examen (respectivement P < 0.02 et P < 0.01). Aucune irritation muqueuse généralisée ni aucune coloration cliniquement significative de la langue ou de dents n’a été notée.


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