Original Article

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A Comparative Study of Fluoride Containing Chlorhexidine and Non-Chlorhexidine Mouthrinses in a Teenage Group

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Abstract

Aim: The study was planned to assess the effect of a mouthrinse containing Chlorhexidine (CHX) and amine/stannous fluoride (AmF) on plaque accumulation, gingivitis and salivary fluoride levels in comparison with two mouthrinses containing either essential oils (EO) or cetylpyridinium chloride (CPC) with sodium fluoride (NaF) in a teenage group.

Methodology: For this study 82 healthy teenage between 13 and 16 years were recruited for participation. The experimental gingivitis model consisted of a 2-weeks recruitment phase, followed by a 6-day rinsing period with one of the 4 mouthrinse formulations was used for the study. At the end of the pre-phase period and the rinsing period (Day-0/Day-6), gingival index (GI), plaque index (PI) and salivary fluoride levels were recorded. The statistical analyses were performed using Wilcoxon sign test and the dependent t test.

Results: A reduction in plaque re-growth was seen for the CHX+AmF formulation rinse, although there were no significant differences among all groups ($p>0,001$). During the experimental periods, the gingivitis indices increased significantly for all formulations ($p<0,001$), except for the CHX+AmF formulation. The CHX+AmF formulation scored higher levels of salivary fluoride at the end of the rinsing period ($p>0,001$).

Conclusion: It reveals that the adjunctive use of AmF containing CHX mouthrinses to mechanical oral hygiene should be recommended for teenage at risk groups.

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Key Words

Mouthrinse, chlorhexidine, fluoride, dental plaque

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Introduction

The removal of bacterial biofilm is a decisive component in the prevention and treatment of periodontal diseases. The use of mechanical agents is a simple and cost-effective method that has been demonstrated to be efficient in infectious oral disease control. But in several individuals, the level of oral hygiene is still insufficient at many sites, or hard-to-reach areas, and it is difficult to provide good plaque control consistent with oral health (1,2). During recent years, the use of antimicrobial mouthrinses as chemotherapeutic adjunct to mechanical oral hygiene regimens has become well established in dental practice for the control of plaque and plaque-induced gingivitis (1). Furthermore, efforts have been made to utilize chemical agents in conjunction with or even instead of mechanical plaque control. A number of enzyme preparations, antiseptics, essential oils and surface

active agents have been examined and used for this purpose (3)

Over the years, studies have showed that chlorhexidine digluconate (CHX) is the most effective antimicrobial agent used for plaque control (3,4,5). However, the side effects of CHX, primarily staining, taste alteration, and enhancing supragingival calculus formation, limit its potential for long-term use, while promoting interest in research to determine the efficacy of alternative antiplaque agents (2,4,5). The three antimicrobial systems classified as safe and efficacious for the treatment of plaque-induced gingivitis by the FDI plaque subcommittee were cetylpyridinium chloride (CPC), amine/stannous fluoride (AmF/ SnF_2), and essential oils (EO) (6). In this context, non-CHX products like EO and CPC that offer an alternative to long-term use are available (7). The mouthrinses containing EO have received much attention, and their antiplaque effectiveness was demonstrated in numerous clinical trials (5,8,9). Similarly, several studies about the use of a CPC as a cationic surface-active agent reported significant improvement in plaque scores and bleeding indices (7).

Fluorides, as caries inhibitory and antiplaque agents, were developed about 40 years ago, and today, the use of fluoride mouthrinses are probably one of the most common methods for prevention of caries and gingival inflammation (3,10). The additional benefits of combining AmF and sodium fluoride (NaF) to CHX in order to prevent plaque accumulation and gingival health has rarely been evaluated (11,12). Recently, non-CHX-NaF products are available, and one of the advantages of this kind of products is its suitability for long-term use (11). On the other hand, there is no literature available on the comparative effect of mouthrinses containing either CHX or non-CHX in combination with AmF or NaF on plaque accumulation, gingival inflammation, and salivary fluoride levels. Hence, the present study was planned to assess the effect of a mouthrinse containing CHX and AmF on plaque accumulation and salivary fluoride levels in comparison with two mouthrinses containing either EO or CPC with NaF in a group of school children aged 13-16 years.

Materials and Methods

For this study, eighty-two systemically healthy children between 13 and 16 years of age were recruited for participation from Gazi University Faculty of Dentistry Departments of Pedodontics. To qualify, the participants had to have at least 20 teeth, show no signs of periodontal destruction, have no caries or extensive restorations, and have not been exposed to systemic antibiotics during the past 6 months.

This randomized, double-blind placebo-controlled clinical study was conducted in a parallel group design. Prior to the study, ethical approval was obtained from the Ethics Committee of the Faculty of Dentistry, University of Gazi, Ankara, Turkey. The experimental gingivitis model consisted of a 2-week recruitment phase, followed by a 6-day rinsing period during which each participant abstained from all mechanical plaque control measures, but rinsed twice daily with one of the 4 mouthrinse formulations (Table 1) (10, 12). The CHX formulation (Elgydium Fluoride mouthwash, Pierre Fabre Oral Care, France) was used as a positive control rinse, and the 0.9% sodium chloride (NaCl) formulation was used as the negative control rinse.

The treatment protocol requested 3 visits from each participant in the study center. At the first visit, the participants underwent a professional tooth

Table 1. Factors examined in the study.

Group Name	Product Name	Manufacturer	Ingredients	Fluoride Type/Level
Group 1	Oral-B Tooth & Gum Care Mouth Rinse	Procter&Gamble Company, USA	Cetylpyridinium Chloride, Mint Flavour	Sodium fluoride (0.05%) (226ppm F)
Group 2	Elgydium Fluoride	Pierre Fabre Oral Care, France	Fluorinol, Chlorhexidine, Siliglycol.	Amine fluoride (250ppm F)
Group 3	Listerine Fluoride	Johnson & Johnson Healthcare Products Division of McNEIL-PPC, Inc. USA	Water, Sorbitol Solution, Potassium Sorbate, Flavors, Poloxamer 407, Sucralose, Citric Acid, Cetylpyridinium Chloride, FD&C Blue	Sodium fluoride (0.0221%) (0.01% w/v fluoride ion)
Group 4	Control/Placebo	Eczacıbaşı, Baxter, Turkey	0.9% NaOCl	

cleaning and oral hygiene instructions were followed for a 2-week period in which the subjects were asked to practice a high standard of plaque control at home. All subjects were given the same toothpaste and toothbrush (Colgate-Palmolive Company, USA) (13). Neither the subjects nor the examiners knew which formulation was assigned to a subject. All of the groups were delivered in identical opaque white bottles. All subjects entering the rinse phase had a mean age of 14.01 years (range 13-16 years) and included 36 female and 24 males. No significant differences were revealed in the demography of the groups.

At the end of the pre-phase period, gingival index (GI) and plaque index (PI) were assessed and recorded as baseline examinations, followed by a professional tooth cleaning in the Department of Periodontology at the same university (Day-0). 60 subjects who had a GI ≤ 0.5 were then selected to enter the rinse phase of the study. Then, in the Department of Pedodontics, the saliva samples were collected from subjects under close supervision no earlier than two hours after a meal between 9:00 and 12:00 to evaluate the fluoride concentration of the saliva as baseline examination (Day-0). Prior to collection of each sample, the subjects were asked to sit and relax. The paraffin-stimulated saliva was collected for five minutes in a graduated sampling tube and transported to the laboratory in ice. The use of the study products was explained to the subjects by an individual not involved in the clinical data recording.

The first rinsing was performed under supervision in the study center. The subsequent rinsing was performed by the subjects at home each morning and evening (7:00-9:00 AM, 5:30-7:30 PM) during the 6-day study period. The use of additional mouthrinse preparations, dentifrices, and mechanical tooth cleaning measures was not allowed. The participants were randomly divided into four treatment groups of 15 subjects and rinsed with 10 ml. of the study product for 1 min twice a day. The subjects were instructed not to eat, drink, or rinse for 30 min. following the rinse. On day 6, subjects received a re-examination of their oral soft and hard tissues and were scored for PI and GI (Day-6). Immediately after recording the indexes, to determine the fluoride level, stimulated saliva samples were collected and fluoride ion activities were measured (Day-6).

Investigated Parameters

Following clinical indices (at baseline and after the rinse phase of the study, Day-0 and Day-6), data were recorded for monitoring the plaque accumulation and gingival situation of the participants before and after the rinse phase of the study: Turesky Modification of Quigley-Hein Plaque Index (TMQHP) with the use of a 0.2 % erythrosine disclosing agent and gingival index (GI) (13). All clinical parameters were measured with a William's probe calibrated in millimeters.

Salivary fluoride levels (at baseline and after the rinse phase of the study, Day-0 and Day-6) were also assessed, and the fluoride ion activities were measured by means of a fluoride ion-specific electrode (Model 94-09, Orion Research, Inc., Cambridge, MA) and a reference electrode. The electrodes were immersed in buffered water between periods of use and were equilibrated in a suitable buffer standard NaF solution immediately before use.

Standard buffered NaF solution was used to calibrate the electrodes. A minimum of five minutes of equilibration time was allowed before meter readings were recorded. Before the fluoride analysis, one part of the TISAB buffer (Total Ionic Strength Adjustment Buffer) was added to one part of saliva (2 ml TISAB buffer to 2 ml saliva sample). This study was performed in a non-fluoridated area (in Ankara) where the fluoride concentration was about 0.1±0.01 ppm in the local drinking water.

Statistical Analysis

A data analysis was performed using SPSS for Windows, version 11.5 (SPSS Inc., Chicago, IL, United States). The Kruskall-Wallis test was used to measure the fluoride, plaque index, and gingival index levels. In the event of significant results, the Mann-Whitney U test was used for comparisons between two groups. A p value < 0.05 was considered statistically significant.

Results

All subjects satisfactorily completed the rinsing regimens. The impact of all mouthrinse formulations on the plaque formation, together with the reduction rate in the plaque index is summarized in Table 2. A reduction (Day-6/Day-0) in plaque index was seen for the CHX+AmF formulation rinse, although there were no significant differences among all groups ($p>0.05$).

The GI of each group at the beginning and end of the rinsing period is shown in Table 3. During the experimental periods, without oral hygiene but with the use of different mouthrinses, the gingivitis indices increased significantly for all formulations ($p<0,05$), except for the CHX+AmF formulation, which showed a statistically insignificant increase at the endpoint (Day-6) ($p>0.05$).

The impact of the different mouth rinse formulations on the salivary fluoride levels is shown in Table 4. When the change in salivary fluoride levels over time (Day-6/Day-0) was considered in each group, the CHX+AmF formulation scored higher levels of salivary fluoride at the end of the rinsing period (p>0,05), when compared to the other formulations. Conversely, salivary fluoride level changes among all groups were significant over time (Day-6/Day-0) (p<0.05).

Table 2. Effect of mouthrinses on 6-Day plaque re-growth

Mouth Rinse	Day-0	Day-6	p[a]	Changes in Plaque Re-growth	p[b]
Oral B	0,57 (0,33-1,07)	1,84 (1,50-2,09)	<0,001	1,19 (0,82 – 1,37)	0,784
Elgydium	0,68 (0,34-1,14)	1,64 (1,39-2,09)	<0,001	1,2 (0,62 – 1,50)	
Listerine	0,57 (0,28-1,22)	1,75 (1,38-2,24)	<0,001	1,0 (0,66 – 1,30)	
Control	0,35 (0,22-0,65)	1,61 (1,30-2,23)	<0,001	1,05 (0,78 – 1,70)	

a. Comparisons intra-group (Wilcoxon İşaret testi).
b. Comparisons between groups (Kruskal Wallis testi).

Table 3. Changes in gingival index scores over time (Day-0/Day-6**)**

Mouth Rinse	Day-0	Day-6	p[a]	Changes in Gingival Index Scores	p[b]
Oral B	0,02 (0-0,16)	0,24 (0,15-0,33)	<0,001	0,13 (0,08 – 0,24)[c]	0,002
Elgydium	0,13 (0,10-0,42)	0,16 (0,10-0,26)	0,842	0,01 (-0,08 – 0,08)[c,d,e]	
Listerine	0,09 (0,06-0,13)	0,21 (0,11-0,32)	<0,001	0,13 (0,07 – 0,21)[d]	
Control	0,12 (0,07-0,14)	0,20 (0,16-0,25)	<0,001	0,11 (0,06 – 0,14)[e]	

a. Comparisons intra-group (Wilcoxon İşaret testi).
b. Comparisons between groups (Kruskal Wallis testi).
c. Statistically significant difference between groups Oral B and Elgydium (p<0,001).
d. Statistically significant difference between groups Elgydium and Listerine (p<0,001).
e. Statistically significant difference between groups Elgydium and Control (p=0,002).

Table 4. Differences in salivary fluoride levels (Day-0/Day-6).

Mouth Rinse	Day-0 /ppm	Day-6/ppm	p[a]	Changes in Salivary Fluoride Levels /ppm	p[b]
Oral B	0,13 (0,11-0,17)	0,11 (0,10-0,12)	0,012	-0,02 (-0,05 – 0)[c,d,e]	<0,001
Elgydium	0,19 (0,11-0,55)	0,29 (0,13-0,65)	0,002	0 (-0,10 – 0,10)[c,f,g]	
Listerine	0,40 (0,16-0,71)	0,12 (0,11-0,31)	<0,001	-0,24 (-0,40 – -0,04)[df,]	
Control	0,09 (0,08-0,12)	0,01 (0,01-0,01)	<0,001	-0,07 (-0,11 – -0,05)[e,g]	

a. Comparisons intra-group (Wilcoxon İşaret testi).

b. Comparisons between groups (Kruskal Wallis testi).
c. Statistically significant difference between groups Oral B and Elgydium (p<0,001).
d. Statistically significant difference between groups Oral B and Listerine (p<0,001).
e. Statistically significant difference between groups Oral B and Control (p=0,029).
f. Statistically significant difference between groups Elgydium and Listerine (p<0,001).
g. Statistically significant difference between groups Elgydium and Control (p<0,001).

Discussion

The effective control of dental plaque is an essential factor for continuity of oral health. The adjunctive use of antimicrobial mouthrinses in mechanical oral hygiene measures was shown to be of value in inhibiting or reducing plaque formation. A number of antimicrobial mouthrinses are intended to prevent or reduce the accumulation of dental plaque when used daily (2,5). The cationic antiseptic CHX has often been used as a positive control during the assessment of other agents potential on plaque accumulation and gingival bleeding (14). However the side effects limit its duration of use, so recently, alternative non-CHX formulations such as EO and CPC have become a current issue promising better tolerance and similar efficacy (5,15).

Researchers have suggested that fluoride enters into the plaque directly or indirectly (3,16). The retention of fluoride in the mouth after application of dental products such as dentifrices and mouthrinses may be associated with an oral fluoride reservoir. Such a reservoir may serve as storage for fluoride, which releases its contents into saliva gradually, and fluoride that is present in the mouth in a labile form is likely to be the most beneficial. As a result of this common knowledge, both fluoride and CHX containing mouthrinses have come into the market sugessting that they inhibit the development of dental caries and plaque (3,16). Jayaprakash et al. (3) demonstrated that the use of mouthrinse with the CHX-NaF combination in addition to mechanical cleaning had better results than both mechanical cleaning alone or in combination CHX containing mouthrinse in the means of reducing plaque and gingival index scores, at the end of the 6 month.

Joyston-Bechal and Hernaman (17) revealed that the combination of fluoride and CHX has been very effective on both plaque and gingival bleeding. Recently, non-CHX fluoride containing products are available with a long-term usage advantage and have been used as supplements to regular tooth cleaning (16).

The present study was designed to determine the short-term plaque inhibiting effect of AmF containing CHX mouthrinse compared to two of non-CHX NaF containing mouthrinses. Two non-CHX containing mouthrinses, one containing a fixed combination of 4 essential oils and NaF and the other containing CPC and NaF, were included in the comparative plaque and gingivitis re-growth study reported herein.

In accordance with Jayaprakashi et al. (3), the teenage subjects are known to often practice inadequate oral hygiene measures and experience gingivitis, but rarely demonstrate symptoms of periodontal destruction. It is a typical first screening method for the evaluation of fluoride-containing mouthrinses in different ways (salivary fluoride levels, gingival and plaque indices). In the absence of mechanical oral hygiene procedures, the 6-day (short-term) plaque re-growth study is conducted. Similarly, in several studies, a short-term plaque re-growth model was used to assess the chemotherapeutic plaque inhibitory activity of different formulations (1,8,9,13,18).

The experimental gingivitis and dental plaque accumulation models are acknowledged as the best design to prove both plaque accumulation and gingival health effects of active components in mouthrinse preparations, as shown in numerous clinical studies (13,18,19).

A number of studies have examined salivary fluoride levels after application of fluoride-containing mouthwashes. In all these, cases salivary fluoride levels were examined after a single use of such treatments (16,20,21). Unlike previous studies, in this study, the fluoride release into saliva by NaF and AmF containing mouthrinses was compared over a 6-day washout period.

Consistent with other studies (4,11,12,14), in the present study, the major plaque changes were recorded with CHX-containing products, but no significant differences were found among all groups (p>0,001). This result may be explained by the significantly lower beginning plaque scores of the negative control group or the dosage of the CHX (0.02 %). Also, it should be considered that before being examined, the patients used the products at home not in the study center. Due to these factors, EO-, CPC-, and CHX-containing mouthrinses had similar effects on plaque accumulation. There are very few clinical trials that could be compared directly with the present study (19,22). For example, Brecx et al. (19) reported similar plaque indices in the placebo and in the CHX group at the start (day 1) and endpoint (day 21) of the clinical trial. Another study suggested equivalent activity for EO mouthrinse with a CHX mouthrinse (22). Similarly, a

CPC rinse was reported to be as effective as an EO rinse at inhibiting plaque accumulation (23,24). The results of the present controlled clinical study show that performance of non-CHX preparations are very comparable to the so-called "gold standard" (25), CHX containing mouthrinses.

On the other hand, the statistical analysis revealed a clear-cut difference between the CHX group and all three non-CHX containing mouthrinse preparations with respect to GI and salivary fluoride levels. Moreover, the CHX group showed similar GI at the start (day 0) and endpoint (day 6) of the clinical trial. The significant difference may be due to the effect of AmF. A significant amount of evidence is available that supports that fluoride exposure from mouthrinses with AmF or NaF was sufficient to build up reservoirs of fluoride (26, 27,28). Qgaard et al. (28) revealed that fewer lesions and decreased gingival inflammation developed on the upper anterior jaw in the AmF-containing mouthrinse group compared with that of NaF containing.

The improved gingival inflammation inhibiting effect of AmF compared with NaF products may be due to several factors. AmF products have a lower pH (4-5) than NaF (pH 6-7) products. It is well established that the major reaction product formed on enamel during short exposures, such as rinsing, is a calcium fluoride-like material (26). At neutral pH, this calcium fluoride is contaminated with phosphate and has a higher rate of dissolution than calcium fluoride with less internal phosphate formed at a lower pH.

However, a calcium fluoride material with less internal phosphate is less soluble than fluoraapatite, and this may be a significant factor since plaque pH is generally lower and hence clearances of fluoride with lower pH (AmF) can occur faster in the plaque (27). In accordance with current information, AmF containing CHX rinse group build up a statistically significant reservoir of fluoride in the saliva.

Conclusion

The present study showed that, contrary to expectations, CHX containing mouthrinse had no significantly greater effect on plaque accumulation than the other groups. However, the reduction of GI values and salivary fluoride levels were significantly greater in the combined AmF-CHX rinse group.

Although further long-term studies are needed to support our current data, present results suggest that the adjunctive use of mouthrinses for mechanical oral hygiene is promising for controlling gingival inflammation for teenage at-risk groups.

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The authors deny any conflicts of interest related to this study.

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