

Original Research Article

Original research article: A Comparative Study of Fluoride Containing Chlorhexidine and Non Chlorhexidine Mouthrinses in a Teenage Group

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Abstract: Brushing and flossing alone, in the absence of rinsing with antiplaque agents, can in theory control plaque growth purely by mechanical removal action on the accumulated plaque. However in reality many patients do not achieve the desired professional goal of an adequate and consistent control of dental plaque. 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. For this study 92 healthy teenage between 15 and 20 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. 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 ($p>0.001$). In conclusion, adding chlorhexidine mouth rinse to daily oral hygiene reduces bacterial plaque accumulation and improve the gingival index. Chlorhexidine mouth rinse appears to be more effective than the normal home care for improving the appearance of white spot lesions over a 3 months period.

Keywords: Brushing, antiplaque agents, gingivitis, Chlorhexidine

INTRODUCTION

Orthodontic treatments may induce oral ecologic changes, leading to increase of *Streptococcus mutans* in saliva and plaque [1]. Orthodontic brackets play a significant role in gathering microbial plaque. Caries-preventive measures, good oral hygiene, noncariogenic diet, and regular fluoride supplementation are often insufficient in preventing the occurrence of new carious lesions in orthodontic patients with high caries activity. Also, it has been shown that orthodontic treatment with fixed appliances results in enamel demineralization and increased numbers of carious lesions, predominantly in sites adjacent to brackets [2].

Over the years, studies have showed that chlorhexidine digluconate (CHX) is the most effective antimicrobial agent used for plaque control [3-5]. 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. 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/ SnF₂), and essential oils (EO) [6].

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

This prospective study was conducted at Ahmedabad dental college, Ahmedabad, Guajrat from 2013-2016. For this study, eighty-two systemically healthy children between 15-20 years of age were recruited. 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.

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) [7,8]. 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 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) [9]. 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 16.01 years (range 15-20 years) and included 55 female and 25 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 college (Day-0). 80 subjects who had a $GI \leq 0.5$ 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 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 20 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).

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) [10]. 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.

Statistical Analysis

A data analysis was performed using prism software. The Kruskal-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 ($p > 0.05$).

Table 1: Factors examined in the study

GROUP NAME	PRODUCT NAME	MANUFACTURE	INGREDIENT	FLOURIDE TYPE/LEVEL
GROUP 1	ORAL B Tooth & Gum care mouth rinse	Procter & gamble,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	Water sorbitol solution,potassium sorbate,flavors,poloamer 407,sucralose,citric acid, Cetylpyridinium Chloride	Sodium fluoride(0.0221%) (0.01% w/v fluoride ion)
GROUP 4	Control/Placebo	Eczacıbaşı, Baxter, Turkey	0.9% Naocl	

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

Mouth rinse	Day 0	Day 6	p ^a	Changes in Plaque regrowth	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	1,20(0,33-1,50)	
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(0,33-2,23)	<0.001	1,05(0,78-1,70)	

a: Comparison intra group(Wilcon isaret test)
b: Comparison between group(Kruskal wallis test)

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 :Comparison intra group(Wilcon isaret test)
b : Comparison between group(Kruskal wallis test)
c:stastitically significant difference between Oral B and Elgydium(p<0.001)
d:stastitically significant difference between Listerine and Elgydium(p<0.001)
e:stastitically significant difference between Control and Elgydium(p=0.000)

Table 4: Diffrence in salivary fluoride level(Day 0/day 6)

Mouth rinse	Day 0	Day 6	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}	0.002
Elgydium	0,19(0,11-0,55)	0,29(0,13-0,65)	0.002	0(-0,10-0,10) ^{c,g}	
Listerine	0,40(0,16-0,71)	0,12(0,11-0,31)	<0.001	-0,24(0,40-0,04) ^{d,f}	
Control	0,09(0,08-0,12)	0,01(0,01-0,01)	<0.001	0,07(0,11-0,05) ^{e,g}	

a :Comparison intra group(Wilcon isaret test)
• Comparisons between groups (Kruskal Wallis testi).
• Statistically significant difference between groups Oral B and Elgydium (p<0,001).
• Statistically significant difference between groups Oral B and Listerine (p<0,001).
• Statistically significant difference between groups Oral B and Control (p=0,029).
• Statistically significant difference between groups Elgydium and Listerine (p<0,001).
• Statistically significant difference between groups Elgydium and Control (p<0,001).

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) ($p<0.05$).

DISCUSSION

Plaque accumulation and subsequent gingivitis are common in orthodontic patients because of the challenge of controlling oral hygiene with the combination of brackets, bands, wires and elastomeric ligatures. Poor oral hygiene can eventually lead to the formation of white spot lesions, decay and hyperplastic gingival tissue that may require intervention by a general dentist upon the completion of orthodontic treatment [11].

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 [12,13]. 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 [15].

Researchers have suggested that fluoride enters into the plaque directly or indirectly. The retention of fluoride in the mouth after application of dental products such as dentifrices and mouth rinses 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 mouth rinses have come into the market suggesting that they inhibit the development of dental caries and plaque. Jayaprakash *et al* [16] 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 mouth rinse 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 .

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 Jayaprakash *et al.* [16], 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 [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 [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 [20]. 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.

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. Qgaard *et al.* [21]. 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.

CONCLUSION

In conclusion, adding chlorhexidine mouth rinse to daily oral hygiene reduces bacterial plaque accumulation and improve the gingival index. Chlorhexidine mouth rinse appears to be more effective than the normal home care for improving the appearance of white spot lesions over a 3 months period.

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