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Effectiveness of a chlorhexidine dentifrice in orthodontic patients: a randomized-controlled trial

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Abstract

This blind and randomized-controlled trial analysed chlorhexidine dentifrices in relation to dental plaque, gingivitis, bleeding, calculus and enamel extrinsic staining development. Volunteers in fixed orthodontic therapy used the following dentifrices: 1100 ppmF, NaF (group A, $n = 27$); experimental, 1100 ppmF, NaF and chlorhexidine 0.95% (group B, $n = 28$); and experimental, chlorhexidine 0.95% (group C, $n = 28$). At baseline, after 6, 12 and 24 weeks, clinical examinations were carried out. The gingivitis, bleeding and plaque data were tested by ANOVA and Tukey's post hoc tests. Stain and calculus data were analysed by Kruskal–Wallis and Dunn's post hoc tests ($p < 0.05$). Plaque, gingivitis and bleeding scores improved in all three groups, but up to the 6 and 12 weeks examination the products containing chlorhexidine were statistically better. The chlorhexidine dentifrices significantly increased the mean of the stain index, although most of the patients did not notice the stains. The calculus index was not significantly modified. In summary, this study suggests that the use of dentifrices containing chlorhexidine seems to be effective for the treatment of gingivitis in orthodontic patients, although the intense motivating contact that the volunteers had with the researchers may have also played a role.

Key words: chlorhexidine; dentifrice; orthodontics; randomized-controlled trial

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Orthodontic treatment with fixed appliances in particular alters the oral environment. There is an increase in plaque around bands and brackets (Pender 1986), the composition of the flora changes (Lundström & Krasse 1987) and cleaning becomes more difficult for the patient (Olympio et al. 2003). As a result, gingival inflammation and enamel decalcification around fixed appliances can result if preventive programmes are not implemented (Zachrisson 1977).

Chlorhexidine is a bis-biguanide with antimicrobial properties, having a special affinity for oral structures. It has a long history as a substance for inhibiting plaque formation and reducing the number of bacteria in the oral cavity, including streptococci, which are associated with the development of caries lesions (Rijkom et al. 1996). It is widely used in clinical dentistry (Gjermo 1974, Addy 1986). Mouthwashes are the most commonly employed forms and many commercial products are sold in several countries. Other vehicles such as gels (Zickert et al. 1982), sprays (Francis et al. 1987) and varnishes (Heintze et al. 1998b) are also used. Although chlorhexidine is widely utilized, the use of chlorhexidine dentifrices has not been adequately explored. Attempts to formulate chlorhexidine dentifrices were made and some studies have been conducted (Gjermo & Rolla 1970, 1971, Gjermo & Eriksen 1972, Johansen et al. 1972, 1975, Dolles & Gjermo 1980). These studies cause doubts because many ingredients commonly added to the dentifrices, such as anionic detergents, interact and inactivate the chlorhexidine. Indeed, the study by Yates et al. (1993) has shown favourable results for chlorhexidine. Thus, the aim of this study was to evaluate the effect of chlorhexidine dentifrices in relation to dental plaque, gingivitis, bleeding, calculus and enamel extrinsic staining development.

Material and Methods

The Institutional Review Board of Bauru Dental School, University of São Paulo, reviewed and approved this research. Volunteers participated after signing an informed consent.

Dentifrices

The dentifrices assessed in this study were: A – fluoride dentifrice commercially available in Brazil (Sorriso Fresh, 1100 ppm F, NaF, Kolynos do Brasil Ltd™, Osasco, Brazil); B – experimental dentifrice containing 1100 ppm F, NaF and chlorhexidine 0.95% (FGM™,

Joinville, Brazil); and C – experimental dentifrice containing chlorhexidine 0.95% (FGM™). The composition of experimental dentifrices was 0.95% chlorhexidine digluconate, hydroxypropylmethylcellulose, silica, Tween 60, glycerin, flavorins and water.

Experimental protocol

The design of this study was blind, characterizing a randomized-controlled trial. The aim of this study was to evaluate the active products in a normal home usage study of 6-month duration. The American Dental Association guidelines for the evaluation of oral hygiene products for the control of plaque and gingivitis (Council on Dental Therapeutics 1985) were followed. For the volunteers' recruitment, a total of 752 charts of patients attending Orthodontics Clinics of the Bauru Dental School, University of São Paulo and Association of São Paulo State Dentists, Brazil, were investigated. The phone number, name and address of patients that had permanent dentition and presented treatment scheduled for more than 6 months at least were registered. By phone, these people were invited to participate in a meeting to explain the 6-month clinical study. The aim of the study was also described in a Written Information Letter, which was supplied to the parents and participants. Respondents were informed that they would be suitably assessed at an initial screening examination.

After this previous meeting, the subjects were recruited to baseline examinations. At baseline screening, all subjects included were aged between 13 and 32 years. The inclusion criteria were complete dentition, good general health, and absence of pharmacotherapics use for at least 3 months, pregnancy or smoking habits. Furthermore, all the volunteers presented a minimum level of pre-existing gingivitis [score 1 of the gingival index (GI), Löe & Silness 1963]. The examinations were performed by two previously calibrated examiners (K. P. K. O. and P. A. P. B.). This initial sample was maintained to achieve group sizes of approximately 30 at the commencement of the study. This sample size was calculated to demonstrate at least a difference of 20% among the groups. Based on the screening scores, the participants were randomly allocated to three treatment groups balanced for gender, GI and plaque index (PI). For this, the participants were stratified for gender, GI and PI and the allocation was made by means of a draw. This kind of randomization was chosen because it slightly increases the power of a small sample size assay, which is due to the reduction of the variation of the end-point caused by random disproportion of important baseline variables. However, its main limitation is the small number of baseline variables (no more than two or three) that can be balanced by using this technique (Cummings et al. 2003).

The following data were recorded blindly: (1) extrinsic stain of the dental enamel by area (Addy et al. 1983); (2) criteria for calculus of the simplified oral hygiene index (Greene & Vermillon 1964); (3) GI (Löe & Silness 1963); (4) bleeding index (Ainamo & Bay 1975); and (5) orthodontic PI (Heintze et al. 1998a). One examiner measured the extrinsic stains and calculus indices (CIs; K. P. K. O.) and a second examiner (P. A. P. B.) undertook the other indices. Following the baseline examination, the volunteers were seen by a dentist and all supragingival stain, plaque and calculus were removed. Subjects were requested to refrain from having scale and polish during the 6-month study period. However, they were advised that if tooth staining became unacceptable, they could attend the study dentist to have the staining removed by polishing.

Initially, the receptionist delivered a kit containing the dentifrice and a toothbrush. The tubes of dentifrice were delivered after each screening. After 3 months, a new dental toothbrush was reposed by the receptionist. This receptionist controlled the number of tubes used by the volunteers collecting the used tubes and registering this number. This procedure was carried out to check the compliance of the participants. The receptionist retained a copy of the study protocol and individual sealed code breakers. This detail was important because the researchers did not know which dentifrice had been delivered to each volunteer.

Instructions concerning toothbrushing and dental floss use were given to all volunteers. Furthermore, they were instructed to brush three times a day for 2 min., using an amount of dentifrice that covered the head of the toothbrush. Volunteers were also asked not to use other oral hygiene products.

Volunteers returned to the clinic at 6, 12 and 24 weeks after the trial started and the clinical indices scored at baseline were repeated. At each return visit, volunteers received a further prescription about the importance of correctly following the instructions and not using other dentifrices than that supplied for the study. Every 15 days, the receptionist called the volunteers, motivating participation in the trial and dentifrice use. When the volunteers took any microbial chemotherapy, this case was recorded.

A questionnaire was applied to the volunteers at each return. This questionnaire evaluated toothbrushing habits, compliance with the study, intake of chromogenic beverages (Leard & Addy 1997), opinions with respect to the dentifrices and possible uncomfortable effects.

At the end of the study, all volunteers were seen by the dentist and all extrinsic stain, plaque and supragingival calculus were removed.

Statistical methods

GraphPad Instat software was used to process the data. After the data were tested for normality and homogeneity, parametric statistics was applied to gingival, bleeding and dental plaque index (ANOVA with repeated measures and Tukey's post hoc tests, $p < 0.05$). For enamel extrinsic staining and calculus, non-parametric statistic was applied (Kruskal–Wallis and Dunn's post hoc tests, $p < 0.05$). The confidence interval was 95%

Results

Of the 752 charts assessed, a total of 128 subjects were screened by phone. From these, 92 attended the meeting and 85 fulfilled the criteria to participate in the trial. Two patients withdrew after baseline examination (Fig. 1).

The data were initially tested and the three groups were statistically similar in relation to the five indices (ANOVA, $p < 0.05$). All the participants were included in the statistical analyses (group A, $n = 27$; group B, $n = 28$; and group C, $n = 28$).

Table 1 shows the stain index (SI) means, standard deviations (SDs) and 95% confidence interval (95% CI) for groups A–C at baseline and after 6, 12 and 24 weeks. In relation to long-term results, the control dentifrice A showed similar results in all examinations ($p = 0.79$) and was significantly differ-

ent from the others ($p = 0.0007$). The stains increased in volunteers who used dentifrices containing chlorhexidine and this was maintained until the last examination.

Considering CI, Table 2 presents that there were no significant differences among the examinations or dentifrices ($p = 0.35$). The active ingredient did not increase calculus.

In Table 3, the results of GI show that all the groups improved across the examinations, but groups B and C significantly reduced the GI ($p = 0.006$). At 12- and 24-week examinations, group A presented further improvement in relation to 6-week examination.

The bleeding index results can be observed in Table 4. Up to 12-week examination, groups B and C presented significantly better results, but in the 24-week examination no significant differences among the groups were observed ($p = 0.24$).

Table 5 shows the PI means (SD) and (95% CI) of groups A–C, in relation to the time of examination and the dentifrice used. Significantly lower PI was found for the chlorhexidine dentifrices up to the 6-week examination and the results were maintained after that. Group A presented an additional improvement in the 12-week examination, and this was kept up to the last examination, when no significant differences were detected among the groups ($p = 0.11$).

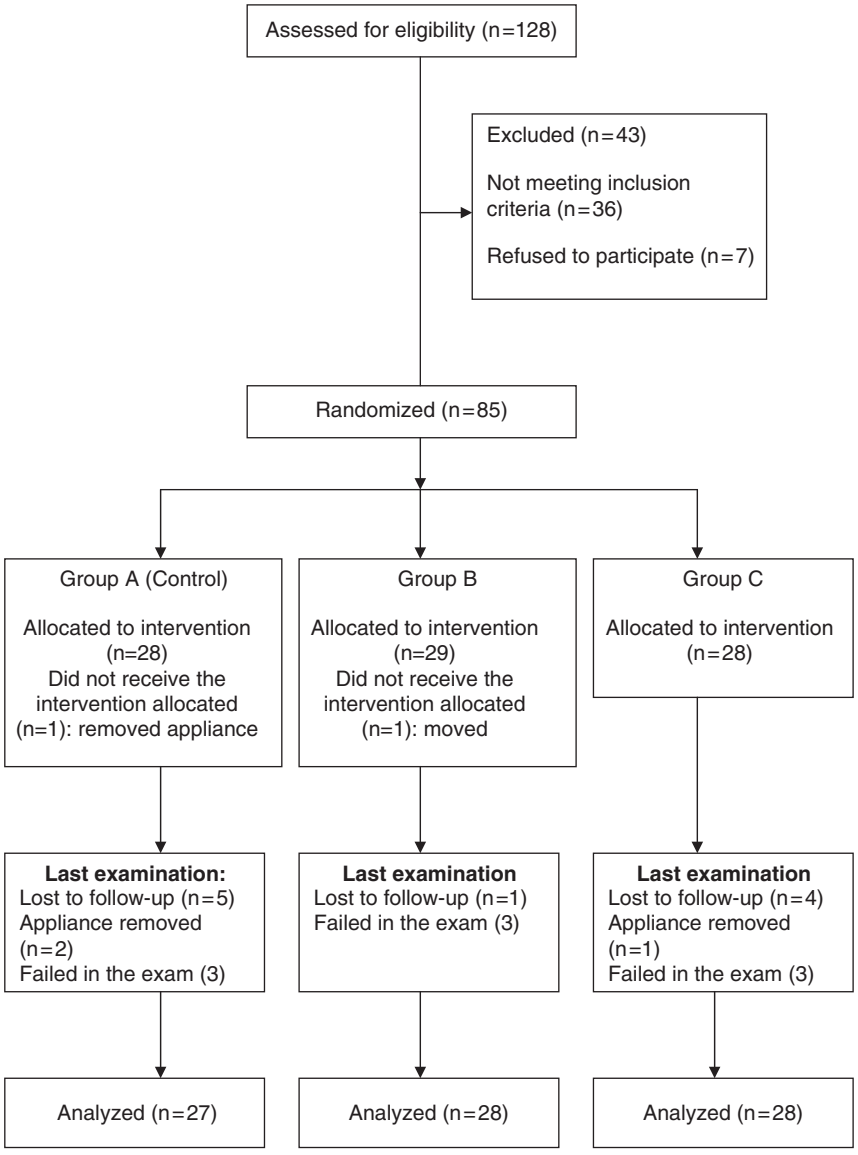

Fig. 1. Flow diagram of the progress through the phases of the study.

Discussion

This clinical trial demonstrated that up to 3 months of the experiment the 0.95% chlorhexidine dentifrices significantly reduced gingivitis, bleeding and PIs in groups of orthodontic patients in relation to a dentifrice without chlorhexidine. The results confirm the findings of an experimental gingivitis study (Jenkins et al. 1993b) and of a previous clinical study (Yates et al. 1993). The reactivity of the chlorhexidine makes the formulation of oral hygiene products containing such agent difficult. However, the results of this study suggest that the formulation used was effective. A significant finding of the study was that the incorporation of fluoride, as sodium fluoride, had no adverse effects. There were no significant differences between the single (chlorhexidine) and double (chlorhexidine and fluoride) active formulations.

Toothstaining is a well-established side effect of chlorhexidine products

Table 1. Stain index (SI) means (SD) and (95% CI) of the groups A–C at baseline and after 6, 12 and 24 weeks utilizing the dentifrices

Group	SI			
	baseline	6 weeks	12 weeks	24 weeks
A	0.4 (1.6)^{a,A} (– 0.3–1.0)	1.4 (4.4)^{a,A} (– 0.3–3.1)	9.2 (27.6)^{a,A} (– 1.7–20.1)	5.3 (17.7)^{a,A} (– 1.7–12.3)
B	3.3 (7.7)^{a,A} (0.3–6.2)	33.7 (54.4)^{b,B} (12.6–54.8)	46.8 (54.1)^{b,B} (25.8–67.8)	31.0 (37.2)^{b,B} (16.6–45.4)
C	1.2 (4.3)^{a,A} (– 0.5–2.9)	39.3 (59.2)^{b,B} (16.3–62.2)	49.3(69.2)^{b,B} (22.4–76.1)	32.1 (52.8)^{b,B} (11.6–52.6)

Different lower case letters in the same column and upper case letters in the same line indicate significant differences among dentifrices and time of screening, respectively (Kruskal–Wallis, $p < 0.05$).

A, fluoride dentifrice ($n = 27$); B, fluoride and chlorhexidine dentifrice ($n = 28$); C, chlorhexidine dentifrice ($n = 28$).

Table 2. Calculus index (CI) means (SD) and (95% CI) of the groups A–C at baseline and after, 6, 12 and 24 weeks utilizing the dentifrices

Group	CI			
	Baseline	6 weeks	12 weeks	24 weeks
A	0.1 (0.1)^{a,A} (0.0–0.1)	0.0 (0.1)^{a,A} (− 0.0–0.1)	0.0 (0.1)^{a,A} (− 0.1–0.1)	0.0 (0.1)^{a,A} (− 0.0–0.1)
B	0.1 (0.2)^{a,A} (0.0–0.2)	0.1 (0.2)^{a,A} (0.0–0.2)	0.1 (0.2)^{a,A} (0.0–0.2)	0.1 (0.2)^{a,A} (0.0–0.2)
C	0.1 (0.2)^{a,A} (0.0–0.2)	0.1 (0.1)^{a,A} (0.0–0.1)	0.1 (0.1)^{a,A} (0.0–0.1)	0.1 (0.1)^{a,A} (0.0-0.1)

Different lower case letters in the same column and upper case letters in the same line indicate significant differences among dentifrices and time of screening, respectively (Kruskal–Wallis, $p < 0.05$).
A, fluoride dentifrice ($n = 27$); B, fluoride and chlorhexidine dentifrice ($n = 28$); C, chlorhexidine dentifrice ($n = 28$).
Score 0: without calculus.
Score 1: supragingival calculus covering up to 1/3 of the exposed surface of the teeth.
Score 2: supragingival calculus covering between 1/3 and 2/3 of the exposed surface of the teeth or a continued and thick band of subgingival calculus.
Score 3: supragingival calculus covering more than 2/3 of exposed surface of the crown or a continued and thick band of subgingival calculus.

Table 3. Gingival index (GI) means (SD) and (95% CI) of the Groups A–C at baseline and after 6, 12 and 24 weeks utilizing the dentifrices

Group	GI			
	Baseline	6 weeks	12 weeks	24 weeks
A	1.2 (0.3)^{a,A} (1.1–1.3)	0.8 (0.3)^{a,B} (0.7–0.9)	0.7 (0.3)^{a,B,C} (0.6–0.8)	0.6 (0.2)^{a,C} (0.5–0.7)
B	1.2 (0.3)^{a,A} (1.1–1.3)	0.5 (0.2)^{b,B} (0.5–0.6)	0.5 (0.2)^{b,B} (0.4–0.6)	0.5 (0.2)^{b,B} (0.4–0.6)
C	1.2 (0.3)^{a,A} (1.1–1.3)	0.6 (0.3)^{b,B} (0.5–0.7)	0.5 (0.2)^{b,B} (0.4–0.5)	0.4 (0.2)^{b,B} (0.3–0.5)

Different lower case letters in the same column and upper case letters in the same line indicate significant differences among dentifrices and time of screening, respectively (Kruskal–Wallis, $p < 0.05$).
A, fluoride dentifrice ($n = 27$); B, fluoride and chlorhexidine dentifrice ($n = 28$); C, chlorhexidine dentifrice ($n = 28$).
Score 0: without inflammation, healthy gingiva, with regular colour.
Score1: Light inflammation, small changes in gingival colour and surface texture.
Score 2: Moderate inflammation, the gingival is moderately red, vitreous, edematous, presenting hypertrophy and bleeding under stimulus.
Score 3: Severe inflammation, the gingival is clearly red, presenting hypertrophy, spontaneous bleeding and ulceration.

Table 4. Bleeding index (BI) means (SD) and (95% CI) of the groups A–C at baseline and after 6, 12 and 24 weeks utilizing the dentifrices

Group	BI			
	Baseline	6 weeks	12 weeks	24 weeks
A	33.3% (16.7)^{a,A} (26.7–39.9)	12.5% (8.7)^{a,B} (9.1–15.9)	12.4%(8.8)^{a,B} (8.9–15.9),	8.1%(4.4)^{a,B} (6.4–9.9)
B	33.0% (16.2)^{a,A} (26.7–39.3)	7.0% (4.3)^{b,B} (5.3–8.6)	6.9% (4.9)^{b,B} (5.0–8.8)	7.2% (8.6)^{a,B} (3.9–10.6)
C	33.7% (19.2)^{a,A} (26.2–41.1)	7.2% (5.5)^{b,B} (5.1–9.3)	6.7% (5.4)^{b,B} (4.6–8.8)	5.3% (5.3)^{a,B} (3.2–7.3)

Different lower case letters in the same column and upper case letters in the same line indicate significant differences among dentifrices and time of screening, respectively (Kruskal–Wallis, $p < 0.05$).
A, fluoride dentifrice ($n = 27$); B, fluoride and chlorhexidine dentifrice ($n = 28$); C, chlorhexidine dentifrice ($n = 28$).
In this index, the sulcus of each tooth is probed. Four sites are measured: facial, lingual, mesioproximal and distoproximal. The presence or absence of bleeding at each site is noted. The number of bleeding sites is the sum of the total bleeding sites divided by the total number of sites.

(Löe & Schiott 1970, Flotra et al. 1971, Flotra 1973, Gjermo 1974) and its occurrence has been shown both in vitro (Addy et al. 1989) and in vivo (Jenkins et al. 1989, Jenkins et al. 1993a) as a measure of chlorhexidine activity. Similar to an experimental gingivitis study (Jenkins et al. 1993b), toothstaining was observed with the use of the active products in the present research. Although staining was observed in this study (Table 1), most of the volunteers did not perceive it. Contrarily, considering groups B and C, 16.5% and 40.4% of the volunteers reported that their teeth were whiter at 6- and 24-week examinations, respectively. During the whole study period, only 5.7% related to perceive their tooth as yellowish or dark. However, Gründemann et al. (2000) studied the effects of the adjunctive use of an oxidizing agent peroxyborate to chlorhexidine to reduce the toothstaining in rinses. They concluded that the proportion of stained surfaces was significantly less when adding the oxidizing mouth rinse to chlorhexidine. Thus, the use of this agent should be tested with dentifrices containing chlorhexidine.

The compliance of the volunteers in this study can be considered as adequate. Considering the answers to the last questionnaire, 70.9% of the volunteers related to have brushed their teeth three times a day. Also there were no reports of soft tissue exfoliation or interference on the taste. A few volunteers reported of the bitter taste of the dentifrices containing chlorhexidine (3.9%).

The present study does not support previous reports that the use of chlorhexidine products increases supragingival calculus formation. The early short-term studies suggested reduced calculus formation with chlorhexidine (Löe et al. 1971, Cancro et al. 1972), but most long-term investigations

Table 5. Plaque index (PI) means (SD) and (95% CI) of the groups A–C at baseline and after 6, 12 and 24 weeks utilizing the dentifrices

Group	PI			
	Baseline	6 weeks	12 weeks	24 weeks
A	83 (12)^{a,A} (78–87)	65 (10)^{a,B} (61–69)	55 (19)^{a,C} (48–63)	52 (18)^{a,C} (45–59)
B	78 (12)^{a,A} (74–83)	51 (14)^{b,B} (46–57)	45 (16)^{a,C} (39–51)	43 (16)^{a,C} (37–50)
C	82 (11)^{a,A} (78–87)	48 (14)^{b,B} (43–54)	48 (14)^{a,B} (43–54)	48 (13)^{a,B} (43–54)

Different lower case letters in the same column and upper case letters in the same line indicate significant differences among dentifrices and time of screening, respectively (Kruskal–Wallis, $p < 0.05$).

A, fluoride dentifrice ($n = 27$); B, fluoride and chlorhexidine dentifrice ($n = 28$); C, chlorhexidine dentifrice ($n = 28$).

In this index, the presence or absence of plaque at each site (cervical, central and occlusal) is recorded. The number of sites with plaque is added, and theses totals are multiplied by factors: one for the coronal, two for the cervical and three for the archwire section of a given tooth. The ortho-plaque index is the sum of the resulting numbers divided by number of teeth present $\times$ 6 $\times$ 100^{-1}.

Good: 0–25 points.

Average: 26–50 points.

Poor: >50 points.

indicated increased calculus accumulation (Löe et al. 1976, Lang et al. 1982, Grossman et al. 1986). In this study, chlorhexidine use did not alter calculus formation.

In fact, gingivitis, plaque and bleeding scores were reduced at 6 weeks and the scores were maintained up to the end of the study, when chlorhexidine dentifrices were used. This improvement almost certainly reflected a Hawthorne effect, consequent upon knowingly involving people in an oral hygiene clinical trial, rather than a benefit conferred directly by the control dentifrice (Jenkins et al. 1993a). This effect occurred in all three groups. In group A, PI and GI presented further improvement at 12-week examination, and this was maintained up to 24-week examination. The bleeding index showed statistically similar results at 24-week examination for all three groups. These facts reinforce the importance of introducing patients in an educative–preventive programme, during the orthodontic treatment. The chlorhexidine dentifrice is an important adjuvant during the treatment, while the patient does not acquire healthy habits of oral health. The dentist must follow its use because the stains need to be removed, whenever it is necessary.

The best results were achieved at 6 weeks and maintained up to the end of the study. The 6-month period of this study is justified by the guidelines for the evaluation of such products (Council on Dental Therapeutics 1985).

In summary, this study demonstrated the effectiveness of dentifrices containing chlorhexidine and fluoride as an adjuvant treatment for gingivitis in orthodontic patients. The utilization of dentifrices containing chlorhexidine can be prescribed until the patient acquires adequate oral health habits. The motivation caused by the contact of the researchers with the volunteers reinforced the responsibility of patients for their own health.

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Clinical Relevance

Chlorhexidine dentifrices can be a simple method to treat gingivitis because they do not modify the patients' routine. The present study demonstrated the effectiveness of chlorhexidine dentifrices for reducing gingivitis in orthodontic patients. Furthermore, the results of this study indicate that the inclusion of patients in an educative and preventive programme keeps them motivated for oral hygiene habits, thus preventing caries and periodontal diseases during the orthodontic treatment.