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An efficacy and safety analysis of a chlorhexidine chewing gum in young orthodontic patients

Jan Cosyn and Kathleen Verelst

Department of Periodontology, School of Dental Medicine, Free University of Brussels (VUB), Brussels, Belgium

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Abstract

Aim: The objective of the present study was to investigate the impact of a chlorhexidine (CHX) chewing gum in teenage orthodontic patients on plaque levels, gingival bleeding tendency and tooth staining.

Materials and Methods: A randomized-controlled, double-blind, parallel study was conducted on 31 teenagers in fixed orthodontic therapy. Subjects of the CHX gum group were asked to continue their oral hygiene procedures in conjunction with chewing two pieces of a 5 mg CHX-containing chewing gum for 10 min. twice a day for 3 months. Subjects of the placebo gum group received the same instructions; however, using a CHX-free chewing gum. Plaque levels, gingival bleeding on probing and tooth staining were monitored at baseline and subsequently after 1–3 months.

Results: Plaque levels significantly decreased from baseline at lingual/palatal sites in the placebo gum group. In the CHX gum group, a similar, yet non-significant trend was observed. At buccal sites, plaque levels remained unaffected in both groups. Gingival bleeding tendency significantly decreased in both groups, predominantly at lingual/palatal sites. There were no significant between-group differences in any of the efficacy parameters at any time point. However, the increase in staining was nearly five times higher in the CHX gum group.

Conclusions: There seems to be no indication for a CHX chewing gum in teenage orthodontic patients when used as an adjunct to normal oral hygiene practices.

Key words: chewing gum; chlorhexidine; orthodontic patient

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The presence of fixed appliances during orthodontic therapy is associated with an increased risk of enamel decalcification and gingival inflammation (Morrow et al. 1992, Øgaard 1992). These pathologic implications have been explained by quantitative and qualitative ecologic changes in the oral cavity: orthodontic brackets and bands impair proper mechanical plaque removal and increase the number of plaque-retentive sites (Zachrisson 1976, Boyd 1983). Consequently, increased proportions and absolute counts of *Streptococcus mutans* in supragingival plaque and saliva can be expected in orthodontic patients (Corbet et al. 1981, Mattingly et al. 1983, Scheie et al. 1984). In addition, a shift towards a more pathogenic subgingval microflora resembling the one usually found in periodontitis patients has been described (Diamanti-Kipioti et al. 1987, Huser et al. 1990).

As most soft tissue reactions are plaque-related, some inflammatory changes have been observed in orthodontic patients with excellent oral hygiene standards (Zachrisson & Zachrisson 1972). This non-plaque-induced inflammation can be explained by the release of cytotoxic corrosion products from the orthodontic appliances (Grimsdottir et al. 1992). Other non-plaque-related conditions in orthodontic patients include traumatic erosive and ulcerative lesions of the oral mucosa (Shaw et al. 1984).

To counteract the tendency of orthodontic appliances to increase plaque accumulation, attempts should be made to keep them as simple as possible, avoiding hooks and elastomeric rings (Forsberg et al. 1991). Still, the key point in controlling the risk of dental and/or periodontal complications remains the patient's compliance in terms of oral hygiene. Especially in youngsters, motivation is of the utmost importance as they are more prone to develop these complications than adults. Indeed, the former have generally shorter clinical crowns and less fully erupted teeth, which may compromise efficient plaque control (Boyd et al. 1989). In addition, elevated hormonal levels during puberty are associated with an increased degree

of gingivitis and gingival hyperplasia (Boyd 1983). Hence, chemical aids are frequently administered in these high-risk populations including a number of vehicles containing fluoride and/or antiseptics.

The objective of the present study was to investigate the impact of a chlorhexidine (CHX) chewing gum in teenage orthodontic patients on plaque levels, gingival bleeding tendency and tooth staining.

Material and Methods

Experimental design

Thirty-one periodontally healthy teenagers (16 males and 15 females) attending an orthodontic practice volunteered for this randomized-controlled, double-blind parallel study. All were in fixed orthodontic therapy according to the Begg method in the upper and lower jaw. This included the application of direct-bonded brackets on the buccal surfaces of all teeth, except for the first molars (and exceptionally also the second molars), which received glassionomer-cemented bands (3M Unitek™, Monrovia, CA, USA). The exclusion criteria were: systemic conditions, antibiotic therapy 6 weeks before or during the study, caries lesions and the presence of more than five inter-proximal restorations. If subjects fulfilled the selection criteria, their parents were informed and a consent form was signed at a screening visit in case of participation.

Orthodontic therapy was systematically preceded by a thorough prophylaxis. Immediately following the application of the fixed orthodontic appliances, which was carried out 2–6 months before the start of the study, oral hygiene instructions were given by one and the same clinician. All patients were provided with the same orthodontic toothbrush (P35, Oral B Laboratories, Isleworth, UK), inter-dental bristles (∅2.5 mm, Oral B Laboratories, UK) toothpaste (Elmex®, GABA BV, Almere, the Netherlands) and mouthwash (Elmex®, GABA BV). Oral hygiene was reviewed at each re-assessment and, if necessary, reinforced.

At baseline, efficacy and safety parameters were recorded by one and the same calibrated clinician. Thereupon, a prophylaxis was performed and patients received a code number randomly assigning them to the CHX gum group (16 patients) or the placebo gum group (15 patients). The allocation to one of these groups was concealed from both the clinician and the patient. Table 1 shows that both groups were comparable with respect to gender and age. The study protocol was approved by the Ethical Committee of the University Hospital in Brussels.

Table 1. Demographic details

Group	No. of patients	No. of males	No. of females	Age (mean ± SD)
Chlorhexidine gum group	16	9	7	12.4 ± 1.59
Placebo gum group	15	7	8	12.3 ± 1.75

Study groups

Subjects of the CHX gum group were asked to continue their oral hygiene procedures in conjunction with chewing two pieces of a CHX chewing gum (Fertin A/S, Vejle, Denmark) for 10 min. twice a day after brushing/meal during 3 months. This chewing gum is delivered in 800 mg pieces containing 447 mg sorbitol as a sweetening agent and 5 mg CHX diacetate.

Patients of the placebo gum group were given the same instructions; however, in this group a CHX-free chewing gum (Fertin A/S) was used. Except for the absence of CHX, this placebo gum is identical in composition to the CHX gum.

At baseline and at the re-assessment visits after 1 and 2 months, patients were provided with a registered and sufficient number of chewing gums to consume during the following month. In order to evaluate compliance, they were asked to collect all gum packings and to bring them at each re-assessment.

Examination criteria

The following response parameters were recorded in a sequential order by the same trained clinician at baseline, and subsequently after 1, 2 and 3 months:

1. The staining index (SI) by Sabzevar (1996b) was recorded on the buccal and lingual/palatal surfaces of the incisors in the upper and lower jaw. This interval-scaled index combines planimetric and photographic techniques to assess the amount of tooth staining. In brief, the outline of the stained tooth surface is manually drawn on a form representing the buccal and lingual/palatal tooth surfaces provided with a superimposed grid of 4 mm × 4 mm squares, the latter being used as reference points during drawing. From these records, black India ink tracings of all stained areas are produced per tooth surface of all incisors in a constant position on a transparent sheet. In addition, tracings are made from the outlines of the buccal and lingual/palatal surfaces of these teeth in the same constant position. Subsequently, all images are digitized with a video camera (AxioCam MRc, Carl Zeiss, Oberkochen, Germany) in order to perform Automatic Image Analysis. Using the KS400 (Zeiss) software and a macro, the total tooth surface area is determined by the closed contour line. For each tooth surface, the total stained surface area is then calculated as the sum of all quantitated surfaces in a single tooth field and expressed as a proportion of the total tooth surface area (%). The technique was found to be highly reproducible as described by Sabzevar (1996b).
2. The bleeding on probing index (BoPI) was measured at six sites (mesial, central, distal buccally as well as orally). The scores ranged from 0 to 2: 0 = no bleeding; 1 = point bleeding within 10 s; and 2 = abundant bleeding within 10 s.
3. The plaque index (PI) Quigley and Hein (1962) was measured at six sites (mesial, central, distal; buccally as well as orally) following plaque disclosure using red Rondell Disclosing Pellets (Svenska®, Väsby, Sweden). The scores ranged from 0 to 5.

All recordings were made without access to previous measurements to avoid measurement bias.

At study termination, all patients were asked to respond to a set of questions regarding chewing gum taste, adherence and hardness by means of a questionnaire.

Sample size calculation

Calculations were based on data from a previous study on the clinical efficacy of

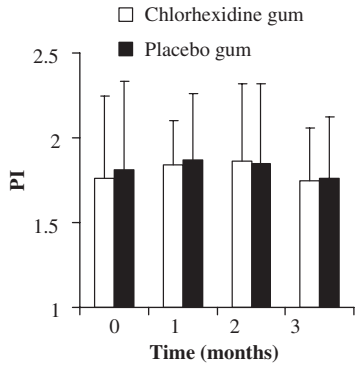

Fig. 1. Changes in plaque levels over time. The data are depicted per group (chlorhexidine gum group *versus* placebo gum group).

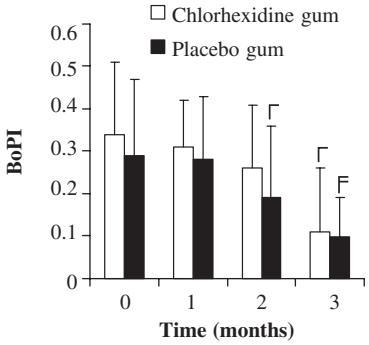

Fig. 2. Changes in bleeding on probing tendency over time. The data are depicted per group (chlorhexidine gum group *versus* placebo gum group). Within-group differences: $0.005 < p \leqslant 0.05$; $p \leqslant 0.005$ (between baseline and follow-up visits).

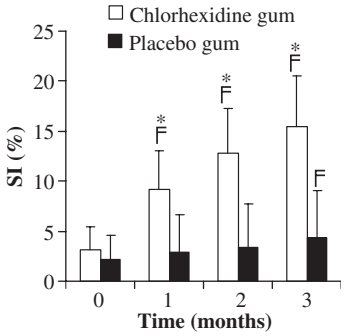

Fig. 3. Changes in tooth staining over time. The data are depicted per group (chlorhexidine gum group *versus* placebo gum group). Within-group differences: $p \leqslant 0.005$ (between baseline and follow-up visits). Between-group differences: $^{*}p \leqslant 0.005$.

the CHX chewing gum in periodontal maintenance patients (Sabzevar 1996a) and a proposed comparison of two means using the independent samples *t*-test. We defined a difference in the primary outcome variable PI of 0.5 between the groups as clinically significant. Using a significance level of 5% and a statistical power of 80% gave a sample size of 15 patients per group. We included 16 patients in the CHX gum group and 15 patients in the placebo gum group.

Calibration session

The clinician charged with clinical assessments was calibrated for PI recordings before the start of the trial. Three orthodontic patients wearing fixed appliances were enrolled for this purpose. Following plaque disclosure, duplicate measurements ($n = 492$) were collected with an interval of 30 min. between the first and the second recording.

Statistical analysis

Data analysis was performed with the patient as the experimental unit. For all response parameters, the mean values per subject and per visit were calculated. The independent samples *t*-test was applied to detect differences in these parameters between the CHX gum group and the placebo gum group at baseline. The clinical changes over time within each group (within-group comparison) and the impact of the group on these parameters (between-group comparison) were examined by means of repeated measures ANOVA with group, time and their interaction as fixed effects and the patient as a random effect. A model with the measurements at baseline, months 1, 2 and 3 was used to compare the changes over time in the two groups (interaction effect). If a statistically significant difference was observed, post hoc tests were performed to determine its source. In addition, a site-specific similar analysis for the efficacy parameters was performed separately considering buccal sites and lingual/palatal sites, again using the patient as the unit of analysis. The level of significance was set at 5%.

Results

Thirty-one subjects entered the study and all completed it. Compliance in terms of chewing gum use was excellent in both groups as all gum packings were empty at each reassessment.

Intra-examiner repeatability was good for PI (79% identical agreement between first and second recording; Cohen's weighted κ: 0.84).

Plaque levels

There were no significant within-group or between-group differences in full-mouth plaque levels at any examination point (Fig. 1). However, when scrutinizing the data separately considering buccal and lingual/palatal sites per group, plaque levels significantly decreased from baseline at lingual/palatal sites in the placebo gum group, pointing to a reduction of 0.12 at study termination ($p \leqslant 0.05$). In the CHX gum group, however, the reduction of 0.11 at 3-month follow-up was not statistically significant ($p = 0.07$). There were no significant differences in plaque levels at lingual/palatal sites between the groups at any time point. At buccal sites, there were neither significant within-group nor between-group differences in plaque levels (Table 2).

Gingival bleeding on probing

Figure 2 shows the changes in full-mouth gingival bleeding tendency over time in the two groups. In the placebo gum group, a significant decrease of 0.10 from baseline was established after 2 months of daily chewing ($p \leqslant 0.05$). At study termination, the BoPI was significantly decreased from baseline by 0.19 in the placebo gum group ($p \leqslant 0.005$) and 0.23 in the CHX gum group ($p \leqslant 0.05$). There were no significant between-group differences at any examination point. Scrutiny of the data revealed that the largest reductions in gingival bleeding tendency occurred at lingual/palatal sites in both groups: at study termination, BoPI decreased by 0.28 ($p \leqslant 0.005$) and 0.29 ($p \leqslant 0.005$) from initial values in the placebo gum group, respectively, in the CHX gum group. In the placebo gum group, the reduction of 0.12 at buccal sites was also statistically significant ($p \leqslant 0.05$). There were no significant between-group differences in BoPI either at lingual/palatal sites or at buccal sites at any time point (Table 2).

Tooth staining

Figure 3 shows the mean proportion (%) of the total tooth surface area covered by tooth staining over time in the two groups. In the CHX gum group, a significant increase of 6.1% ($p \leqslant 0.005$) in

Table 2. Site-specific changes in response parameters

Response parameter	Group	Buccal sites*	Lingual/palatal sites*
Plaque Index	Chlorhexidine gum group	− 0.05	0.11
	Placebo gum group	0.02	0.12†
Bleeding on Probing Index	Chlorhexidine gum group	0.08	0.29‡
	Placebo gum group	0.12†	0.28‡
Staining Index	Chlorhexidine gum group	− 12.4%‡§	− 12.3%‡§
	Placebo gum group	− 4.7%‡	0.4%

*Mean change from baseline at study termination; positive value = decrease in reference to baseline; negative value = increase in reference to baseline
Within-group differences:
†$0.005 < p \leq 0.05$;
‡$p \leq 0.005$ (between baseline and 3 months follow-up).
Between-group differences:
§$p \leq 0.005$.

reference to baseline was already established after 1 month. Tooth staining systematically increased in this group, pointing to a rise of 12.4% ($p \leq 0.005$) from baseline at study termination. This phenomenon occurred to a comparable extent at buccal (12.4% – $p \leqslant 0.005$) and lingual/palatal sites (12.3% – $p \leqslant 0.005$; Table 2). In the placebo gum group, a significant increase in tooth staining by 2.1% ($p \leqslant 0.005$) was only found at 3 months. Interestingly, this only occurred at buccal sites (4.7% – $p \leqslant 0.005$; Table 2). At 1, 2 and 3 months, tooth staining was significantly higher in the CHX gum group in comparison with the placebo gum group ($p \leqslant 0.005$).

Questionnaire

The results of the questionnaire revealed that eight out of the 16 patients in the CHX gum group disliked the taste of the chewing gum. In the placebo gum group, however, this proportion was considerably lower (three out of 15 patients). In the CHX gum group, five out of the 16 patients and in the placebo gum group, three out of the 15 patients reported no adherence of the chewing gum to their brackets, which is a relatively comparable proportion. In the CHX gum group, 10 out of the 16 patients and in the placebo gum group, eight out of the 15 patients claimed that the chewing gum was too hard to chew, which is again relatively comparable.

Discussion

The use of CHX as an effective anti-plaque agent has been established (Addy 1986). Consequently, a number of vehicles containing this chemical agent have been developed, among which a chewing gum. An appealing advantage of this vehicle is its compatibility with daily activities.

The efficacy of CHX is dose related (Cumming & Löe 1973, Jenkins et al. 1994). Short-term clinical studies in healthy adolescents and adults have shown an excellent plaque growth-inhibiting effect when a daily dose of 20 mg is intra-orally delivered by means of chewing two pieces of a 5 mg CHX-containing chewing gum for 10 min. twice a day (Ainamo & Etemadzadeh 1987, Ainamo et al. 1990, Tellefsen et al. 1996, Simons et al. 1999). Interestingly, this anti-plaque effect appeared similar to the effect of a 0.2% CHX rinse for 1 min. two times per day even though using the latter corresponds to a daily dose of 40 mg CHX (Ainamo et al. 1990). In addition, the CHX chewing gum demonstrated similar beneficial effects to plaque and gingivitis levels than a 0.2% CHX solution when using them as an adjunct to existing oral hygiene measures (Smith et al. 1996). These observations are probably related to a longer contact time of a chewing gum in the oral cavity as compared with a mouthrinse, which is imperative from a clinical viewpoint as a lower dose of the active agent may potentially reduce side effects. This was confirmed in a clinical study by Smith et al. (1996): a CHX chewing gum (two pieces of 5 mg used for 10 min. twice a day) significantly induced less tooth staining than a CHX mouthwash (10 ml of a 0.2% rinse used for 1 min. twice per day) in an 8-week observation period.

Besides the effects of a CHX chewing gum in healthy subjects, few have studied its potential in high-risk populations for plaque-related diseases. To our knowledge, this is the first efficacy and safety analysis of a CHX chewing gum used by teenagers in fixed orthodontic therapy as an adjunct to existing oral hygiene measures. The results indicate no impact of using a chewing gum on full-mouth plaque levels in a 3-month period, which seems to contrast earlier findings on the use of polyol gums in orthodontic patients (Isotupa et al. 1995). However, when lingual/palatal and buccal sites were separately analysed, significant plaque reduction was observed at the former in patients using a placebo gum. In the CHX gum group, a similar, yet non-significant trend was observed. The lack of statistical consolidation in the latter is possibly related to variation in toothcleaning efficacy. That is, a slight deterioration in toothcleaning efficacy may affect plaque levels, possibly masking a plaque-reducing effect of a chewing gum. At buccal sites, plaque levels remained unaffected at all times in both groups. These observations suggest that a chewing gum induces a mechanical cleansing effect at lingual/palatal sites. The presence of brackets on the buccal sites may protect established dental plaque from this cleansing effect, explaining the status quo of plaque levels at these sites. In fact, this protective effect by orthodontic appliances was earlier described by Brightman et al. (1991). The lack of a CHX-related additive effect supports the idea that CHX is less effective at removing existing plaque than preventing de novo plaque accumulation (Löe & Rindom-Schiott 1970), even though this has been challenged by others (Corbet et al. 1997). Anyhow, as the results of this study show, incorporating CHX into a chewing gum has no additional value in reducing plaque levels in teenage orthodontic patients.

Our data show a significant reduction in gingival bleeding tendency on probing as a result of using a chewing gum after a 3-month observation period. The largest reductions occurred at lingual/palatal sites in both groups, which is not surprising taking into account the impact of a chewing gum on plaque levels at these sites. Interestingly, as CHX has been found to be effective in the prevention and treatment of plaque-related gingivitis (Löe & Schiott 1970, Löe et al. 1976, Quirynen et al. 2001), incorporating this active agent into a chewing gum does not additionally decrease gingival bleeding tendency, at least not in teenagers in fixed orthodontic therapy.

In contrast to our findings of a CHX chewing gum on plaque and gingivitis

levels in orthodontic patients, significant benefits have been described in other populations at risk. Sabzevar (1996a) concluded that a CHX chewing gum was more effective in reducing plaque and gingivitis levels than a placebo gum or even repeatedly reinforced oral hygiene instructions in periodontal maintenance patients. Similarly, Simons et al. (2001) described a superior effect of a CHX chewing gum on plaque and gingivitis scores in comparison with a xylitol-containing gum in elderly in residential homes who had been using one of these chewing gums for 1 year. The lack of accordance with the results of the present study can be explained as follows: first, orthodontic patients are distinguished from periodontal maintenance patients and elderly by the presence of brackets and/or bands on pratically all teeth. These appliances may not alone facilitate new plaque accumulation; they also protect established plaque from mechanical cleansing, which normally occurs during tooth brushing and mastication (Brightman et al. 1991). Second, the results of the study by Simons et al. (2001) showed high baseline plaque and gingivitis levels, whereas subjects of the present study exhibited low scores: high baseline levels create more potential for improvements and leave more margin for differences to be detected when various strategies are tested. Finally, there is the issue of compliance. In the study by Simons et al. (2001), compliance was verified by filling out a tick chart by the care staff whenever a chewing gum was consumed. In the present study, the number of non-consumed chewing gums was recorded at each reassessment serving as its indicator. In spite of these efforts, compliance can never be fully controlled for especially in terms of contact time of the chewing gum within the oral cavity. This contact time may have been lower for the CHX chewing gum than for the placebo gum in this study, taking into account the fact significantly more subjects disliked its taste. This is important, knowing that the *in vivo* release of CHX from a chewing gum is time related (Ainamo & Etemadzadeh 1987). It has to be anticipated, however, that the intra-oral release of CHX was apparently high enough to induce serious tooth staining in the CHX gum group: the increase in staining from baseline was nearly five times higher in the CHX gum group in comparison with the placebo gum group. It has been shown earlier that this side effect may be reduced by lowering the dose of CHX by 2 mg per piece without even compromising efficacy, at least not in terms of plaque growth inhibition in healthy subjects (Ainamo et al. 1990). Interestingly, staining also significantly increased in the placebo gum group at buccal sites. This is logical, knowing that some staining may develop over time as a result of dietary habits for which we did not control in this study.

In conclusion, the results of the present study indicate that frequent use of a chewing gum as an adjunct to existing oral hygiene measures may reduce plaque levels and gingival bleeding tendency predominantly at lingual/palatal sites in youngsters undergoing fixed orthodontic therapy. However, these clinical parameters do not seem to be additionally reduced when CHX is incorporated as an active agent. What is more, CHX increases tooth staining by nearly a factor 5. Hence, there seems to be no indication for a CHX chewing gum in teenage orthodontic patients when used as an adjunct to normal oral hygiene practices.

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Address:
Jan Cosyn
Department of Periodontology
School of Dental Medicine
Free University of Brussels (VUB)
Laarbeeklaan 103
B-1090 Brussels
Belgium
E-mail: jan.cosyn@vub.ac.be

Clinical Relevance

Scientific rationale: The presence of fixed orthodontic appliances is associated with an increased risk of plaque-related pathology, explaining the need for chemical aids. The aim of this study was to compare a CHX chewing gum with a placebo gum on plaque levels, gingival bleeding and staining in teenage orthodontic patients.

Principal findings: Plaque levels and gingival bleeding decreased at lingual/palatal sites; yet, CHX did not additionally reduce these efficacy parameters. In addition, the increase in staining was five times higher in the CHX gum group.

Practical implications: There is no indication for a CHX chewing gum in teenage orthodontic patients.