Influence of an Herbal Mouthwash on Inflammatory Changes of the Gingiva in Patients with Fixed Orthodontic Appliance

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In patients with multiband appliances, the effectiveness of an herbal extract containing mouthrinse (Parodontax©) was tested for possible reduction of plaque and gingivitis. A total of 40 patients (mean age: 16 ± 2.3 years) with mild to moderate gingivitis participated in this prospective randomized, double-blind clinical study. At baseline (Group 1: Parodontax©, n = 20, mean age: 15.8 ± 2.2 years, Group 2: control, placebo solution, n = 20, mean age: 16.1 ± 2.3 years) caries frequency (DMF-T) and approximal plaque index (API), plaque index (PI), sulcular bleeding index (SBI), papillary bleeding index (PBI) and gingival index (GI) were assessed for the Ramfjord teeth. All subjects were examined at 4-week intervals for a period of 3 months, and all plaque and gingival index scores were reevaluated. At the end of the study, the patients in Group 1 (Parodontax©) showed significantly lower parameters indicative of inflammation than those in the control group. The SBI value in Group 1 was reduced from initially 39% to 8%, the PBI value from 1.07 to 0.17, and the GI value from 1.73 to 0.58. The plaque indices, however, showed no significant differences between the two groups (Group 1: API: 87%, initial value, and 78%, final value; PI: 1.99, initial value, and 1.66, final value; Group 2: API: 91%, initial value, and 83%, final value; PI: 2.66, initial value, and 2.11, final value). This double-blind study showed that usage of an herbal extract containing mouthrinse as an adjunct to mechanical oral hygiene measures seems to be beneficial in gingivitis therapy in patients wearing fixed orthodontic appliances.

Key words: multiband appliance, compliance, gingivitis, prophylaxis, herbal extract containing mouthwash

INTRODUCTION

The objective of orthodontic treatment is the correction of malocclusion. The use of fixed appliances with controlled orthodontic forces results in controlled movements of single teeth or groups of teeth. Fixed orthodontic appliances, however, can also cause undesirable effects. In addition, occasionally root resorption as well as bone resorption can be induced by too much force (Zachrisson and Alnaes, 1973). If oral hygiene is insufficient, higher periodontal probing depths as well as increased signs of gingival inflammation have been reported, which are often intensified by the simultaneous presence of edematous swelling and the presence of pseudopockets (Rateitschak et al, 1968). However, if patients follow optimal hygiene measures, and plaque-free conditions are present, an orthodontic treatment generally does not lead to a permanent attachment loss. According to Ericsson and Thilander (1978), an orthodontic appliance can by itself not lead to subsequent attachment loss, nor can it be considered the primary cause for periodontal disease. The occurrence of gingivitis during orthodontic therapy with fixed appliances, however, has been observed in a large number of patients (Zachrisson and Alnaes, 1973; Zachrisson, 1976; Ericsson and Thilander, 1978; Diedrich, 1981; Flores de Jacoby et al, 1982; Alexander, 1991; Zhang et al, 2002). The use of fixed appliances

in combination with a lack of adequate oral hygiene can certainly be regarded as secondary etiologic factor for the development of gingivitis. The orthodontic appliances with their partly irregular surfaces serve as additional retention sites for the accumulation of plaque, which in consequence leads to an increase in inflammatory reactions. The increased gingival irritation can be attributed to mechanical irritation caused by subgingival placement of the orthodontic bands, as well as to translocation of plaque to the subgingival region due to tooth movement (Lindhe et al, 1975).

The presence of gingivitis as well as an increased amount of plaque can lead to demineralization of the dental hard tissues, and to an increase in the formation of white spots on the smooth surfaces of the teeth. In numerous studies, the frequent occurrence of demineralization was observed in patients after orthodontic treatment; the frequency varied between 2% and 96% (Chang et al, 1997). Other authors could show that patients undergoing orthodontic treatment had an increased salivary flow rate and buffering capacity and a higher salivary pH-value (Steinhard, 1989; Chang et al, 1999). Patients with fixed orthodontic appliances should therefore be regularly examined and strongly encouraged to practice strict oral hygiene in order to avoid or reduce the formation and establishment of microbial plaque.

As an adjunct to mechanical oral hygiene measures, chemical antimicrobial agents seem to offer great benefits in the control of plaque formation. The various mouthwashes, which have already been tested in numerous clinical studies, such as Chlorhexamed©, Meridol©, and Listerine© (Riep et al, 1999; Brecx, 2000; Arweiler et al, 2001; Rosin et al, 2002; Netuschil et al, 2001) are very effective with respect to bactericidal action and plaque reduction, but when used frequently, side effects like tooth discoloration, desquamation and irritation of the oral mucosa can occur (Gjermo, 1989). A possible alternative to conventional CHX-based mouthwashes could be formulations containing herbal extracts or salts as active ingredients. Parodontax© mouthwash contains a mixture of herbal extracts from myrrh, echinacea, and chamomile, and is an effective regimen for reducing gingival inflammation (Pistorius et al, 2003). Yankell et al (1988) were able to show in an in-vitro experiment that the mouthwash Parodontax© inhibited the growth of S. mutans and A. viscosus. However, no advantages of this product in reducing plaque accumulation, especially in patients with fixed orthodontic appliances, have been shown as yet. The purpose of the present study was to examine the effectiveness of an herbal mouthwash (Parodontax©) in reducing plaque and gingivitis in patients with fixed orthodontic appliances (multiband appliances).

STUDY DESIGN AND RESULTS

For this clinical study, a total of 40 patients (15 males, 25 females) with a mean age of 16.1 ± 2.3 years were chosen from the Department of Orthodontic Dentistry. All patients showed mild to moderate gingivitis (gingival index according to Löe and Silness at least grade I; plaque index according to Silness and Löe at least grade I), and they were wearing full-mouth fixed orthodontic appliances (upper jaw and lower jaw) for the duration of the study as part of their orthodontic treatment. All the teeth included in the study (Ramfjord teeth) as well as their neighboring teeth showed multiband appliances for the entire period of the study. Patients with systemic diseases, long-time medication, less than 20 teeth, antibiotic treatment within the last six months, periodontal disease (probing depths B 5mm), as well as pregnant women, were excluded from the study.

The patients were randomly assigned to one of two groups so that 20 each belonged to the test or to the control group. The subjects were informed about the purpose, course and duration of the study and gave their written consent. The study was performed according to the declaration of Helsinki, as revised in Venice (1983). All clinical assessments were done by the same person. At the initial examination the number of Decayed, Missing and Filled Teeth (DMF-T) was assessed. In order to evaluate the periodontal condition the following indices were recorded at the Ramfjord teeth (Ramfjord, 1959): modified approximal plaque index (API) (Lange et al, 1974); plaque index (PI) (Silness, Löe,1964); sulcular bleeding index (SBI) (Lange et al, 1977); papillary bleeding index (PBI) (Saxer et al, 1977); gingival index (GI) (Löe, Silness, 1963); and probing depths (probing assessment at 6 different locations per tooth).

After the evaluation of the initial examination, each patient received, depending on the assign-

ment to which group, either the mouthwash concentrate Parodontax© (Parodontax©, GlaxoSmithKline GmbH Bühl, Germany) or the placebo formulation (sterile saline with menthol oil, GlaxoSmithKline GmbH Bühl, Germany). All mouthwash concentrates were filled into identical bottles, in accordance with the double-blind design of the study (GlaxoSmithKline GmbH Bühl, Germany). All participants received the manufacturer's instructions for preparing the prescribed dosage (5 ml to 100 ml H_20). The mouthwash was to be used at the appropriate dilution for 60 seconds twice daily after tooth brushing, and without rinsing afterwards. At study entry, the participants also received a medium hard toothbrush (Oral B© Indikator 35, Oral B, Frankfurt / Main, Germany). The additional usage of other devices for oral hygiene such as dental floss or interdental brushes was not permitted for the duration of the study. Since the presence of gingivitis was a necessary criterion for inclusion, no professional tooth cleaning was performed. Furthermore, no particular instructions concerning oral hygiene or other prophylactic measures were given over the entire period of observation, and all subjects were supposed to continue practicing oral hygiene as they usually do.

The reevaluations were performed 4, 8 and 12 weeks after baseline. The indices API, PI, SBI, PBI and GI were recorded, and the subjects were again instructed about regular use of the mouthwash. In addition, at each visit the intraoral soft tissues were examined so that the possible occurrence of side effects could be recognized in time. At the final examination after 3 months, the subjects filled out a questionnaire to reflect their individual evaluation concerning taste and effectiveness of the mouthwash they used.

For the evaluation of the fixed variables, mean values, median, minima and maxima were calculated as descriptive statistics. In order to evaluate the respective findings, the differences between the values at baseline and the individual control visits were calculated. The Wilcoxon test was used to determine significant differences in the measured parameters between Group 1 and 2 (Parodontax© mouthwash and control group). The level of significance was set at 5%.

Of the total of 42 participants with fixed orthodontic appliances that were accepted, 40 persons (25 females, 15 males, age 16 ± 2.3 years) completed the study. One female patient reported that she could not tolerate the taste and left prematurely, another patient reported serious health problems and had to be excluded from further participation. The mean age of the subjects in the group using herbal extracts was 15.8 years (13 females, 7 males), that of the subjects in the control group was 16.1 years (12 females, 8 males). At study entry, all subjects were wearing fixed appliances for orthodontic treatment for 12 to 18 months (mean duration of wear: 14 months).

At the beginning, the persons in the test group showed an API mean value of 87%, a plaque score of 1.99, an SBI value of 39%, a PBI value of 1.07, and a GI value of 1.73. At the beginning, the participants in the control group showed an API mean value of 91%, a PI of 2.26, an SBI value of 34%, a PBI of 0.88, and a GI value of 1.63. Thus, the values for the two groups did not differ from each other significantly ($p = 0.32$).

The use of the herbal extract containing mouthwash showed a steady improvement of the gingival conditions in the experimental group, whereas the placebo showed no improvement in the inflammatory parameters or just a slight improvement, but no significant change (Figs. 2, 3, 4, 5). At the beginning, the group with the herbal extract containing mouthwash showed an SBI mean value of 39%, which decreased to a mean value of 8% after 12 weeks. The PBI mean value also decreased from 1.07 at the initial examination to 0.17 after 12 weeks ($p < 0.05$), similar to that of the GI mean value (1.73 at the start and 0.58 after 12 weeks).

However, in the control group the SBI decreased only slightly from 34% to 33%. The PBI and GI in the control group changed also only slightly (0.88 at baseline and 0.8 after 12 weeks; 1.63 at baseline and 1.48 after 12 weeks).

There was a significant difference ($p < 0.0005$, Wilcoxon test) between the groups with respect to the decrease in SBI, PBI and GI after 12 weeks. However, with respect to the reduction of the plaque index values (API and PI) after 12 weeks, no significant differences could be observed (API: $p = 0.90$; PI: $p = 0.24$; Wilcoxon test; Fig.1). While the group using the herbal extract containing mouthwash showed a decrease of the API mean value of 87% (baseline) to 78%, in the control group a decrease from 91% to 83% was recorded. The PI also did not improve significant-

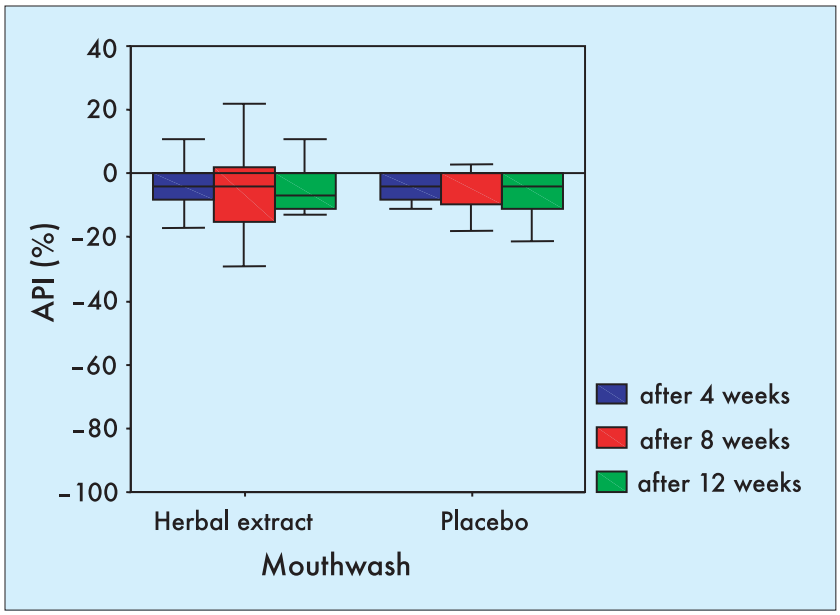

Fig. 1 Approximal plaque index values (API) using an herbal mouthwash (Parodontax®, n = 20) and a placebo solution (n = 20). The observation period was 12 weeks; examinations took place after 4, 8 and 12 weeks.

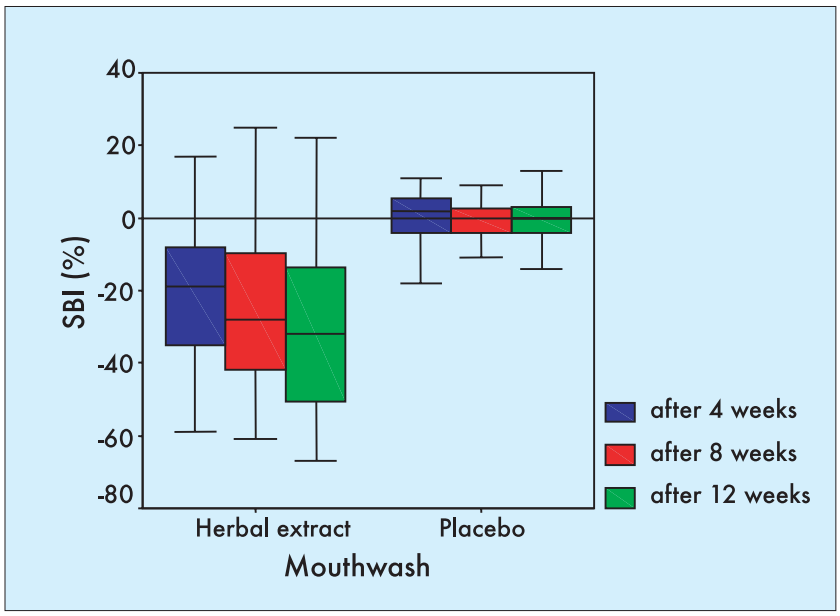

Fig. 2 Sulcus bleeding index values (SBI) using an herbal mouthwash (Parodontax®, n = 20) compared to a placebo (n = 20). The duration of the study was 12 weeks; examinations took place after 4, 8 and 12 weeks.

ly in either one of the groups (decrease of PI from 1.99 to 1.66 in the group using the herbal extract containing mouthwash, and from 2.26 to 2.11 in the control group). In both groups, the plaque index values after 12 weeks were relatively high, which indicated poor oral hygiene (group using an herbal extract containing mouthwash: API 78%, PI: 1.67; control group: API 83%; PI: 2.11). In more than a third of the patients (n = 14) the API value did not improve after 12 weeks, but had even increased. With regards to the probing depths at the beginning and after 12 weeks, no differences between the groups were observed.

After collecting evidence of the subjective evaluations of the patients by means of a questionnaire the taste of the placebo formulation was rated better than the herbal extract containing product. Most patients rated the taste of the product as too pungent, but indicated a positive feeling of freshness.

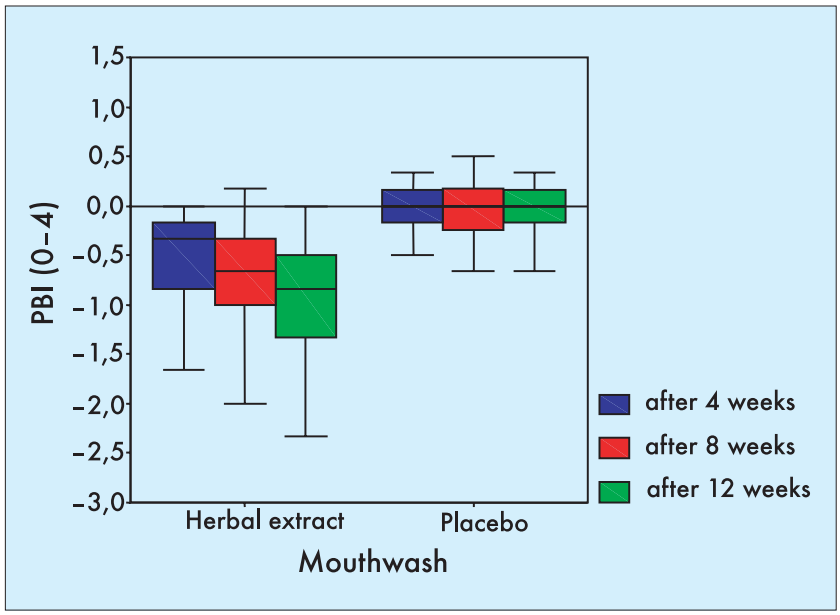

Fig. 3 Papillary bleeding index values (PBI, degree 0-4) using an herbal mouthwash (Parodontax®, n = 20) compared to a placebo (n = 20). The duration of the study was 12 weeks; examinations were after 4, 8 and 12 weeks.

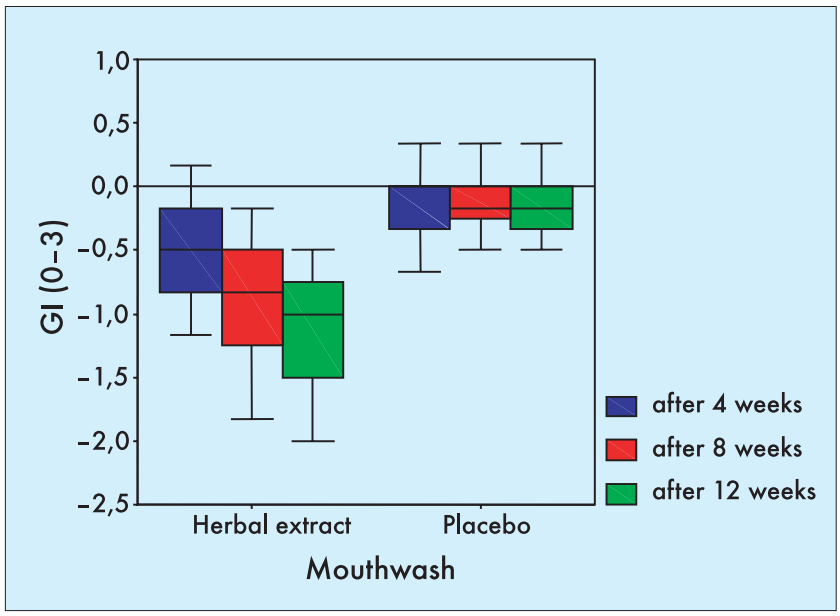

Fig. 4 Gingival Index values (GI, degree 0-3) using an herbal mouthwash (Parodontax®, n = 20) compared to the placebo group (n = 20). The duration of the study was 12 weeks; examinations were after 4, 8 and 12 weeks.

DISCUSSION

It is generally accepted that bacterial plaque is the key etiological factor for inflammatory periodontal diseases (Löe et al. 1965, Listgarten 1976). Besides mechanical plaque reduction, chemical agents in toothpastes or mouthwashes can be used as adjunct oral hygiene measures (Addy, 1986). Many studies have shown the effectiveness of chlorhexidine, various essential oils, stannous/amine fluorides as well as other bisguanide derivatives in dental plaque reduction (Riep et al, 1999; Arweiler et al, 2001; Rosin et al, 2002). Currently there seems to be a trend towards an increase in the use of mouthwashes containing biological substances, without chemical additives. This study examined the effectiveness of a mouthwash, containing solely plant extracts as active ingredients (Parodontax© mouthwash, GlaxoSmithKline GmbH, Bühl, Germany), in patients with fixed orthodontic appliances, suffering from gingivitis. In each patient, gingival inflam-

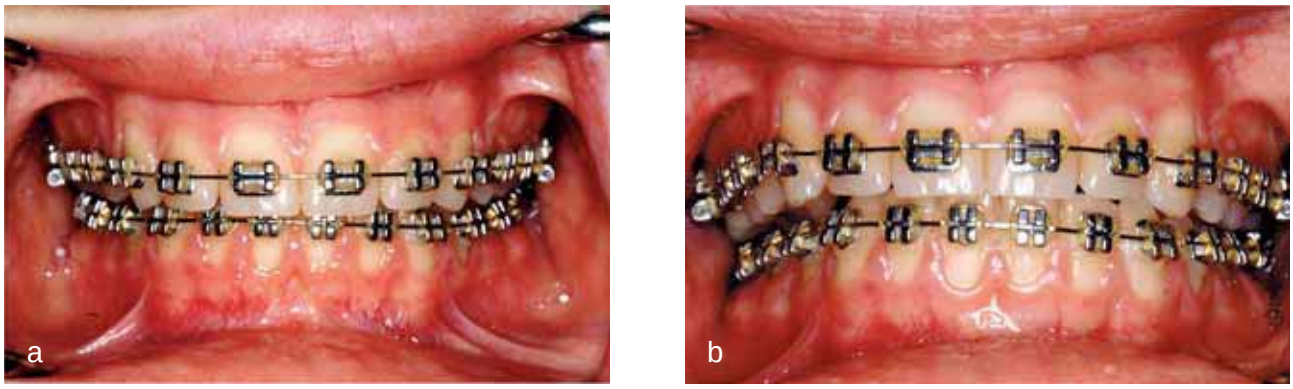

Fig. 5 15-year-old girl with fixed orthodontic appliance (treatment time: 13 months).
(a) Clinical situation at the beginning of the study, and (b) 12 weeks after using an herbal mouthwash (Parodontax®)

mation and plaque accumulation were clinically assessed on the six representative teeth described by Ramfjord. Several studies have shown a high correlation between the scores for the plaque index and the gingival index of the 6 Ramfjord teeth and the scores for the teeth in the rest of the mouth (Ramfjord, 1974; Gettinger et al, 1983). Therefore the Ramfjord teeth are more than adequately representative for the rest of the dentition (Fleiss et al, 1987) and often used in clinical and epidemiological studies.

The results of this study showed a significant improvement in the herbal extract group in all inflammatory indices (SBI, PBI and GI) while the control group did not show any improvement. The anti-inflammatory effect achieved in this study may be contributed to the herbal supplements in the mouthrinse and their physiological properties. Thus, chamomile contains salicylic acid in the form of a methyl ester, which is an anti-inflammatory agent. Furthermore myrrh is reported to be an astringent, and echinacea can influence the immune system (Schauenburg and Paris, 1977). A positive influence of an herbal extract containing mouthwash on gingivitis therapy was confirmed by Itic and Serfaty (1988) and they also demonstrated a beneficial effect on the subgingival flora. The effectiveness of herbal extract containing mouthwashes can be partly attributed to the presence of antiphlogistic and antibacterial ingredients of the respective plant extracts (e.g. sage, chamomile, myrrh) (Scherer et al, 1998).

The antibacterial properties of chamomile, echinacea, myrrh and rhatania on anaerobes have been demonstrated repeatedly (Kitagaki et al, 1983; Willershausen et al, 1991; Shapiro et al, 1994). However, this study showed that no significant reduction in dental plaque could be achieved by using an herbal extract containing mouthwash. A possible reason seems to be the direct influence of the fixed orthodontic appliances on the rate of plaque accumulation and a more difficult access to the tooth surfaces during oral hygiene. Furthermore, an influence of the orthodontic appliances on plaque composition itself cannot be excluded. Pathological changes in the composition of the subgingival plaque with increased levels of black-pigmented Bacteroides (Diamanti-Kipioti et al, 1987) as well as spirochetes and fusiform bacteria (Petti et al, 1977), following the placement of fixed orthodontic bands, have been reported. Another reason for the insufficient oral hygiene in the subjects of this study could be the age of the patients (average: 16 ± 2.3 years). Young patients during puberty are quite frequently less interested in oral hygiene, which becomes even more difficult to practice in the presence of multiband appliances. The Hawthorne effect of the study participants, as described by Jeffcoat (1992), which often plays a larger role than the therapeutic characteristics of the product, was not observed.

The results confirm similar findings from previous studies which were unable to show an inhibitory effect of Parodontax© on plaque growth (Saxer et al, 1995; Kagermeier-Callaway et al, 2000). However, none of these examinations were performed on patients with fixed orthodontic appliances. Bümmerstede et al (1984) pointed out that it is nearly impossible to achieve complete plaque

removal in the areas around brackets, since the site between bracket and enamel surface is predestined for plaque retention. Lundström et al (1980) attributed the increase in plaque after placement of bands to the incorrect positioning of the tooth brush at these problematic sites. Also, the self-cleansing of the teeth by chewing hard food is no longer possible, because of the hindrance of the multiband appliance.

The results of this clinical study with young patients showed that by the additional use of an herbal extract containing mouthwash during treatment with fixed orthodontic appliances, an effective reduction in gingivitis could be achieved. However, since plaque accumulation is not significantly influenced by using herbal extract containing mouthwashes, mechanical plaque removal is essential. Therefore, optimal mechanical oral hygiene measures and additional professional prophylaxis is necessary in patients undergoing treatment with fixed orthodontic appliances.

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