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ORIGINAL ARTICLE

Caries-preventive and remineralizing effect of fluoride gel in orthodontic patients after 2 years

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Abstract Patients with orthodontic appliances exhibit a higher caries risk, but they are often excluded from preventive studies. Thus, the aim of this observational study was to assess the caries-preventive and remineralizing effect of a high-fluoride gel in orthodontic patients. Two hundred twenty-one orthodontic patients (age, 6–19 years; mean, 13.1±2.3; n=104 with use of a 1.25% fluoride gel weekly at home, 117 participants without) were recruited and followed for 2 years, recording caries (decayed/missing/filled teeth (DMFT)/decayed/missing/filled surface (DMFS), active/inactive lesions), orthodontic treatment, use of fluorides, plaque and gingivitis. Baseline values regarding demographic and clinical parameters were equivalent for the 75 participants using fluoride gel and the 77 individuals of the control group who completed the study. The initial plaque and gingivitis values (approximal plaque index (API), 37%±34 and 42%±39, resp.; papillary bleeding index (PBI), 19%±28 and 22%±27, resp.) deteriorated slightly during the 2-year study (API, 54%/56%; PBI, 25%/28%). The increase in carious defects or fillings was minimal in both groups (fluoride, 0.75 DMFT±1.2, 1.27 DMFS±1.9; control, 0.99±1.3 and 1.62±2.6, resp.) without reaching statistical significance (p=0.12 for DMFT, 0.44 for DMFS). The main statistically significant effect of the fluoride use was the reversal of active initial lesions diagnosed (fluoride group, −0.96±1.82; control, −0.19±2.0, p=0.004), while the number of inactive initial lesions increased (2.3±2.1 and 1.7±2.1, resp.; p=0.02). In conclusion, the weekly application of a fluoride gel in orthodontic patients can reduce their caries activity. Initial caries lesions in orthodontic patients can be inactivated by weekly fluoride gel use at home.

Keywords Fluoride · High caries risk · Initial lesions · Prevention · Orthodontics

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Introduction

Although the caries-preventive effect of fluorides is clearly proven [1], only a few studies exist on the magnitude of this effect in special subgroups, for instance, in orthodontic patients or the handicapped. Often, these groups are explicitly excluded in clinical trials [2, 3], although they are in special need due to their elevated caries risk. Studies evaluating intensified preventive measures demonstrate the difficulties of achieving benefits in high-caries-risk groups [4, 5] and it is unlikely that results from other study populations can be simply extrapolated.

According to insufficient data on orthodontic patients, a systematic review of fluorides for the prevention of white spots on teeth during fixed appliance treatment could only draw conclusions on the use of fluoride rinses [5]. In spite of the well-known problem of increased caries activity with fixed orthodontic appliances, adequate caries prevention is not routinely implemented [6]. Older studies, such as a preventive programme with fluoride gel in the 1980s in Hungary [7], are no longer valid today due to an increase in other preventive measures, for instance, greater use of sealants or fluoride exposure and subsequent caries decline.

Thus, the aim of the present study was to assess the caries-preventive and remineralizing effect of fluoride gel in orthodontic patients. As a positive effect of additional

fluoride use could be expected, only an observational study was feasible for ethical reasons.

Materials and methods

After approval by the ethics committee in 2006, participants for this prospective 2-year observational study were recruited in the orthodontics department of the University in Greifswald, Germany, which largely treats ordinary patients, and an orthodontic private practice in Greifswald. Inclusion criteria were children and adolescents with fixed and removable orthodontic appliances with at least 2 years of future treatment planned. Patients with severe dental hard tissue disorders, special needs, insufficient compliance (infrequent use according to interview at recall visits) or an adverse reaction (none observed) to fluoride gel were excluded. The use of fluoride gel at home was assessed at the initial examination and assignment to the fluoride or control group was based on this.

After information on the study and the confirmation that the patients wanted to proceed with or without using fluoride gel, the patients registered in the study and a clinical examination was performed by one calibrated, blinded dentist (AT) in a fully equipped dental chair (light, compressed air). This included the dichotomized bleeding on probing (mod. papillary bleeding index (PBI)) [8] using a perio probe (PCP 8, Hu-Friedy, Chicago, IL, USA) and the approximal plaque index (API) [9] after staining with Miratone (Hager & Werken, Duisburg, Germany). Then, a brushing instruction followed which removed the stained visible plaque. Afterwards carious defects, fillings and teeth missing due to caries (DMFT/S) were recorded according to WHO criteria [10]. Active and inactive initial caries lesions were assessed according to Nyvad et al. [11]. The differentiation between active and inactive lesions is based on the etiological concept of caries: Active lesions require mature plaque which demineralises the enamel. This process can be diagnosed by a chalky white and rough appearance of the lesion. If these lesions are inactivated by regular plaque removal, they arrest or remineralise which leads to a polished and shiny, smooth appearance often accompanied by a shift to a darker colour [11]. In addition to these clinical parameters, a fluoride history was taken.

Semi-annually, both groups received a free manual toothbrush, oral hygiene instructions (AT) and a free toothpaste sample (1,450 ppm). In the fluoride group, the patients were asked if they used the fluoride gel on a regular basis. The answer was recorded as dichotomized variable (mostly yes/no); additional fluoride gel (12,500 ppm, elmex Gelée, GABA, Lörrach, D) was provided free of charge, and its weekly application was encouraged. In the control group, the home use of fluoride gel was excluded. The final examination after 2 years was performed by another trained and calibrated examiner (CS) recording the same clinical parameters as at the baseline examination (inter- and intra-examiner reproducibility, kappa 0.82–0.89, double examination of 10 patients).

Statistical analyses

As the data base for caries prevention with fluoride gels in orthodontic patients is very small and older studies with higher caries levels could not be used for a sample size calculation, the sample size was estimated according to the preventive effect assessed in an American study [12]. The expected mean caries incidence was 1 DMFT for 2 years, with about 0.8 for the fluoride group and 1.2 for the controls. Standard deviations in the range of the respective DMFT values and a power of 80% resulted in study groups of 78 participants each for the final analysis and a group size of about 100 at baseline to compensate for dropout.

The primary outcome variables were DMFT/S and initial lesions (caries incidence) during the course of the study. In the initial descriptive statistical analysis (PC/SPSS 11.5), the primary outcome variables and clinically relevant parameters such as age, gender, plaque, bleeding on probing and fluoride use were calculated and compared between the fluoride and control groups. Due to the mostly non-normal distribution, non-parametric tests were used for the group comparisons at a significance level of 0.05. Categorical data were analysed with the Chi-square test. The data for the caries prevalence were compared to a representative German survey in schoolchildren [13].

Results

From January to August 2006, 221 orthodontic patients were recruited, of whom 104 used fluoride gel at home on a regular basis. One hundred seventeen participants who did not use fluoride gel comprised the control group (Table 1). After 2 years, 152 participants took part in the final examination, 75 of the fluoride group and 77 controls indicating a similar dropout in both groups.

Fluoride and control group

The mean age was similar for the fluoride and control groups at baseline (12.8±2.3 and 13.6±2.4, resp.; range, 7–19 years). After exclusion of the dropout, these values became even closer (12.9 and 13.3). The mean age at the final examination was 14.8±2.3 for the fluoride group and 15.3±2.4 for the control group (range, 9–20 years). The gender distribution was almost identical at baseline (50% and 51% female, resp.) and shifted slightly due to dropout (57% and 46%).

Table 1 Data of full fluoride and control group at baseline and for those children who completed the study

	Complete baseline sample		Baseline data for children who completed study		*p* value (for sample completing the study)
	Fluoride group	Control group	Fluoride group	Control group	
n	104	117	75	77	
Age (mean±SD)	7–18 years (12.8±2.3)	7–19 years (13.6±2.4)	7–18 years (12.9±2.2)	7–18 years (13.3±2.3)	0.12
Gender	50% female	51% female	57% female	46% female	0.42
Full fluoride toothpaste (≥1,250 ppm)	100%	97%	100%	99%	0.32
Fixed orthodontics	78%	88%	71%	80%	0.46
Plaque index (API)	37%±34	42%±39	39%±35	45%±38	0.61
Bleeding on probing (mod. PBI)	19%±29	26%±34	19%±28	22%±27	0.70
DMFS	2.47±3.7	2.50±2.9	2.8±3.9	3.2±5.0	0.50
% Fillings in DMFS	87%	86%	82%	81%	0.64
Active initial lesions	1.3±1.8	1.4±2.1	1.4±1.9	1.6±2.4	0.63
Inactive initial lesions	0.9±1.9	0.7±1.3	0.9±1.9	0.8±1.4	0.29

Most participants had fixed orthodontic appliances in both groups at baseline (78% and 88%, resp.), which decreased slightly by the final examination, due to more removable appliances in the retention phase (55% and 60%, resp.). The daily wearing regimen of the removable appliances reached from constant to only nightly incorporation.

At baseline, four participants in the control group still used children's toothpaste (500 ppm). After an instruction, all participants used adult toothpaste for the course of the study (1,250–1,450 ppm). The use of fluoridated salt increased from about 50–100% both in the fluoride and the control groups during the study.

Oral hygiene scores

Oral hygiene parameters, such as plaque scores and gingival bleeding, were comparable in both groups at baseline. The API for the fluoride and control groups at baseline (37%±34 and 42%±39, resp.) did not change significantly after exclusion of the dropout (39% and 45%). During the course of the study, plaque scores increased slightly to almost identical values (54%±28 and 56%±27, resp., $p=0.72$). The data for the gingivitis scores (PBI) were equivalent, with a mean of 19%±29 for the fluoride group and 26%±34 for the controls at baseline. After exclusion of the dropout, the gap even narrowed to 19%±28 and 22%±27, respectively ($p=0.24$), indicating similar oral hygiene patterns in the fluoride and control groups. For the final examination, these values increased slightly to 25%±19 and 28%±21, resp. ($p=0.27$). Participants with removable or fixed orthodontics showed very similar plaque and gingivitis scores ($p>0.5$).

DMF scores

Initially, both groups showed low caries scores of 1.5±1.8 and 1.8±2.5 DMFT at a mean age of 13 years, which were comparable to representative national German data (12-year olds, 0.7–1.4 DMFT in different federal states) [13]. After exclusion of the dropout, the mean baseline scores were 1.6 (±2.1) for the fluoride group and 2.0 (±2.6) for the controls, which increased to 2.36 (±2.5) and 2.96 (±2.9), resp. after 2 years.

The components of the DMFT did not show significant variation between the two groups with very few cavitated lesions (DT) and fillings comprising the largest segment (>86%). The DMFS data showed the same picture of almost identical mean values at baseline (2.47±3.7 and 2.50±2.9, resp.), which shifted slightly due to dropout (2.8±3.9 and 3.2±5.0, resp.). After 2 years, the values increased to 4.0±4.8 in the fluoride group and 4.8±6.0 in the controls.

Fillings as a major component increased in the children who completed the study from 2.3±3.4 to 3.7±4.5 and 2.6±4.0 to 4.0±4.6, resp. The low number of initially 0.16±0.6 in both groups decreased even further to no carious defect in the fluoride group and 0.08±0.4 in the controls.

Due to the significantly lower age of participants with removable appliances, their mean DMFT/DMFS values were also lower than in their older counterparts with fixed orthodontics. Still the caries increment did not differ for both groups (DMFT $p=0.47$, DMFS 0.78).

Initial carious lesions

The mean number and distribution of active initial carious lesions at baseline was very similar for children of the

fluoride and control groups who finished the study (1.4 ±1.9 and 1.6±2.4). Participants with removable or fixed orthodontics had almost identical numbers of initial caries lesion (p=0.95). After 2 years, this number decreased clearly in the fluoride group (0.5±0.8), but only marginally in the controls (1.4±2.0), resulting in a statistically significant difference of the reduction (0.96±1.8 and 0.19±2.0, resp.; p=0.01).

Regarding inactive initial lesions, the low mean numbers at baseline (0.9±1.9 and 0.8±1.4, resp.) increased in both groups, but especially in the fluoride group (3.2±2.7 and 2.5±2.3, resp.). Here also no statistically significant difference was found between removable or fixed orthodontics at baseline or during the course of the study (p>0.5).

Changes in clinical scores

The participants who completed the study in the fluoride gel or the control group had exhibited similar plaque, gingivitis and caries scores at baseline. During the course of the study, plaque and gingivitis scores in both groups increased slightly (Table 1), indicating a deterioration of oral hygiene. The marginally higher increase of the plaque levels in the fluoride group resulted in almost identical plaque and gingivitis scores in both groups at the final examination (p=0.7).

At the end of the study, all caries parameters showed a more favourable trend for the fluoride group than for the controls (Table 2). The changes in the mean numbers of active initial carious lesions showed a clear, statistically significant difference in favour of the fluoride group (−0.96± 1.8; Table 1), while the controls exhibited a minimal decrease (−0.19±2.0; p=0.01). The reduction of active initial lesions was accompanied by an increase in inactive lesions, especially in the fluoride group (2.32±2.1 versus 1.73±2.1, p=0.02; Table 1).

Thus, the caries scores in orthodontic patients with weekly use of fluoride gel at home did increase less than in the control group, but these differences did not reach the level of statistical significance at the DMFT/S level. In contrast, the number of active initial lesions decreased significantly in the fluoride group which was accompanied by an increase in inactive initial lesions.

Discussion

Although orthodontic appliances promote plaque accumulation and increase the caries risk, intensified prevention is often neglected [5]. Several studies have tested the caries-preventive effect of fluoride gels, varnish applications or rinses in orthodontic patients [7, 12, 14, 15]. The quality of many studies is not optimal, and a systematic review on this topic yielded sufficient data only for the caries-inhibiting effect of rinses and GIC-based bracket bonder [16]. Often, orthodontic patients are explicitly excluded from prevention trials [3].

Methodologically, it is difficult to reassess the caries effect of additional fluoride use after the caries decline, as it is ethically problematic to withhold fluoride products in a randomized clinical trial. Therefore, a true-negative control group is sometimes missing [3, 17].

Observational studies are feasible, but they carry the risk of self selection and a potential bias for more preventively oriented participants in the fluoride group. In the present study, the groups with and without weekly use of fluoride gel at home exhibited comparable baseline values for gender, age, caries, orthodontic treatment, use of fluorides as well as oral hygiene habits which can be deducted from plaque and gingivitis scores. During the course of the study, the dropout of less compliant children, especially in the control group, led to even more similar values between the two groups.

The deterioration of the oral hygiene parameters (plaque/ gingivitis) is not in line with the Hawthorne effect. However, the duration of the orthodontic treatment might have led to some slackening in plaque removal efforts. In addition, the mean age of the participants changed from 12 to 14 years, where teenagers might have other priorities than oral hygiene. Finally, the additional data of the study were gained during regular visits to the orthodontist and not via a special invitation for a study visit.

The current study could not repeat the clear, statistically significant reduction in caries increment (DMFT/DMFS) of an older study in Hungary in orthodontic patients using fluoride gel [7]. In contrast to the sample size calculation, the caries increment at the tooth level (DMFT) was low, which corresponded to the constant caries decline in

Table 2 Changes of plaque (API), gingivitis (mod. PBI) and caries indices in 2 years in orthodontic patients with and without weekly use of fluoride gel at home (mean±SD, Mann–Whitney test, two sided)

	API increment	PBI increment	DMFT increment	DMFS increment	Active initial lesions increment	Inactive initial lesions increment
Fluoride group	16%±39	5%±29	0.75±1.2	1.27±1.9	−0.96±1.8	2.32±2.1
Controls	11%±37	7%±31	0.99±1.3	1.62±2.6	−0.19±2.0	1.73±2.1
p	0.60	0.84	0.24	0.44	0.004	0.02

Germany [13]. However, it must be borne in mind that this study was performed with a much higher caries prevalence, which reduces the generalizability to the current low caries levels. In a more recent study, Alexander and Ripa [12] detected a clear caries-preventive effect of fluoride gel applications at home compared to the use of fluoride toothpaste alone. This was one of the few studies where initial lesions were included and the increased fluoride use often resulted in reversals of these initial lesions. This effect agrees with the results of the present study and also the study by Nyvad et al. [11], who employed the expected fluoride effect to validate their system of differentiating between active and inactive (initial) lesions, which was also used in the present study.

In summary, the fluoride gel application in orthodontic patients mostly resulted in a reversal of active to inactive initial lesions. Although the relative differences in the DMFT increment between the fluoride and control group were high, the absolute values were lower than expected. This might be due to the selection of compliant participants staying in a 2-year longitudinal study. In addition, the levels of caries prevalence have declined continuously in Germany, even during the course of the study [13, 18], which makes statistically significant differences on a DMFT or DMFS basis almost impossible for the future. The polarization of the caries distribution and the accordingly high standard deviations exacerbate this problem and strongly call for the inclusion of initial lesions in future preventive studies.

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Conflict of interest The authors declare that they have no conflict of interest.

References

1. Marinho VCC, Higgins JPT, Logan S, Sheiham A (2003) Topical fluoride (toothpastes, mouthrinses, gels or varnishes) for preventing dental caries in children and adolescents. The Cochrane Library Issue 4, CD002782
2. Künzel W, Fischer T (1997) Rise and fall of caries prevalence in German towns with different F concentrations in drinking water. Caries Res 31:166–173
3. Sköld L, Sundquist B, Eriksson B, Edeland C (1994) Four-year study of caries inhibition of intensive Duraphat application in 11–15-year-old children. Community Dent Oral Epidemiol 22:8–12
4. Hausen H, KärkkäinenS SL (2000) Application of the high-risk strategy to control dental caries. Community Dent Oral Epidemiol 28:26–34
5. Benson PE, Parkin N, Dyer FE, Vine S, Shah A (2004) Fluorides for the prevention of white spots on teeth during fixed brace treatment. Cochrane Database Syst Rev CD003809. Review
6. Derks A, Katsaros C, Frencken JE, van't Hoff MA, Kuijpers-Jagtman AM (2004) Caries inhibiting effect of preventive measures during orthodontic treatment with fixed appliances. Caries Res 38:413–420
7. Denes J, Gabris K (1988) Die Ergebnisse eines dreijährigen Elmex-Programms während der kieferorthopädischen Behandlung mit festsitzenden Apparaturen. ZWR 97:863–868
8. Lange DE, Plagman H, Eenboom A, Promesberger A (1977) Klinische Bewertungsverfahren zur Objektivierung der Mundhygiene. Dtsch Zahnarztl Z 32:44–47
9. Lange DE (1990) Parodontologie in der täglichen Praxis. 4. Auflage. Quintessenz, Berlin, p 100
10. World Health Organisation (WHO) (1997) Oral health surveys: basic methods, 4th edn. Oral Health Unit, WHO, Geneva
11. Nyvad B, Machiulskiene V, Baelum V (1999) Reliability of a new caries diagnostic system differentiating between active and inactive caries lesions. Caries Res 33:252–260
12. Alexander S, Ripa LW (2005) Effects of self-applied topical fluoride preparation in orthodontic patients. Angle Orthod 70:424–430
13. Pieper K (2005) Epidemiologische Begleituntersuchungen zur Gruppenprophylaxe 2004. Bonn
14. Derks A, Katsaros C, Frencken JE, Vanthof MA, Knipers-Jagtman AM (2004) Caries-inhibiting effect of preventive measure during orthodontic treatment with fixed appliances. Caries Res 38:413–420
15. Lagerweij MD, Cate JM (2002) Remineralization of enamel lesions with daily applications of a high-concentration fluoride gel and a fluoridated toothpaste: an in situ study. Caries Res 36:270–274
16. Benson PE, Parkin N, Dyer FE, Vine S, Shah A (2004) Fluorides for the prevention of white spots on teeth during fixed brace treatment. Cochrane Database Syst Rev CD003809
17. Øgaard B, Larsson E, Henriksson T, Birkhed D, Bishara SE (2001) Effects of combined application of antimicrobial and fluoride varnishes in orthodontic patients. Am J Orthod Dentofacial Orthop 120:28–35
18. Institut der deutschen Zahnärzte (IDZ) (2006) Vierte Mundgesundheitsstudie (DMS IV) neue Ergebnisse zu oralen Erkrankungsprävalenzen, Risikogruppen und zum zahnärztlichen Versorgungsgrad in Deutschland 2005. Deutscher Zahnärzteverlag, Köln