High-fluoride toothpaste: a multicenter randomized controlled trial in adults

Srinivasan M, Schimmel M, Riesen M, Ilgner A, Wicht MJ, Warncke M, Ellwood RP, Nitschke I, Müller F, Noack MJ. High-fluoride toothpaste: a multicenter randomized controlled trial in adults. Community Dent Oral Epidemiol 2014; 42: 333–340. © 2013 The Authors. Community Dentistry and Oral Epidemiology published by John Wiley & Sons Ltd

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Abstract – Objective: The aim of this single-blind, multicenter, parallel, randomized controlled trial was to evaluate the effectiveness of the application of a high-fluoride toothpaste on root caries in adults. Methods: Adult patients (n = 130, ♂ = 74, ♀ = 56; mean age ± SD: 56.9 ± 12.9) from three participating centers, diagnosed with root caries, were randomly allocated into two groups: Test (n = 64, ♂ = 37, ♀ = 27; lesions = 144; mean age: 59.0 ± 12.1; intervention: high-fluoride toothpaste with 5000 ppm F), and Control (n = 66, ♂ = 37, ♀ = 29; lesions = 160; mean age: 54.8 ± 13.5; intervention: regular-fluoride toothpaste with 1350 ppm F) groups. Clinical examinations and surface hardness scoring of the carious lesions were performed for each subject at specified time intervals (T₀ – at baseline before intervention, T₁ – at 3 months and T₂ – at 6 months after intervention). Mean surface hardness scores (HS) were calculated for each patient. Statistical analyses comprised of two-way analysis of variance and post hoc comparisons using the Bonferroni–Dunn correction. Results: At T₀, there was no statistical difference between the two groups with regard to gender (P = 0.0682, unpaired t-test), or age (P = 0.9786, chi-squared test), and for the overall HS (Test group: HS = 3.4 ± 0.61; Control group: HS = 3.4 ± 0.66; P = 0.8757, unpaired t-test). The ANOVA revealed significantly better HS for the test group than for the control groups (T₁: Test group: HS = 2.9 ± 0.67; Control group: HS = 3.1 ± 0.75; T₂: Test group: HS = 2.4 ± 0.81; Control group: HS = 2.8 ± 0.79; P < 0.0001). However, the interaction term time-point*group was not significant. Conclusions: The application of a high-fluoride containing dentifrice (5000 ppm F) in adults, twice daily, significantly improves the surface hardness of otherwise untreated root caries lesions when compared with the use of regular fluoride containing (1350 ppm F) toothpastes.

Key words: adult; dental caries; Duraphat 5000 ppm F; high-fluoride toothpaste; oral health; prevention; randomized controlled trial; root caries; sodium fluoride

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The advantageous effects of using low concentrations of fluorides (F) on enamel and dentin demineralization are very well documented (1). Fluoridated dentifrices, varnishes, and topical applications have contributed to a widespread decline in dental caries in most developed nations (2–4). Prophylactic fluoride applications have predominantly been indicated in children, and because of the increased risk of fluorosis, the fluoride content is restricted to a lower concentration (5–8). However, the use of low concentration fluoride may be ineffective in decreasing the caries susceptibility in high-risk subjects. High-fluoride interventions have been usually limited to chair-
side topical professional applications. The use of high-fluoride containing varnishes or gels demonstrated a 40% improvement over stand-alone routine oral hygiene measures (9). Although, fluoride varnishes have demonstrated sufficient clinical evidence in the prevention and inhibition of dental caries, a Cochrane review reported that fissure sealants were more effective than varnishes and further emphasized that fluoridated toothpastes produce similar effects as with varnishes, gels, and mouth rinses (10).

Extensive clinical trials on fluoridated toothpastes have concluded that the fluoride content is an important factor in its effectiveness (3). Clinically, increased fluoride content results in increased fluoride levels in plaque films (11). It has been suggested that an increase of 500 ppm F within the range of 1100–2500 ppm F, results in an additional 6% caries reduction (12, 13). Fluoride toothpastes with <1450 ppm F content have been reported to be less effective in high-risk children (14). Hence, it is highly likely that higher fluoride levels in toothpastes would decrease caries incidence more effectively. Adults with multiple coronal carious lesions or multiple root fillings are at increased risks of prevalent untreated root caries, especially elderly individuals with a compromised health status (15). Very few studies have reported the incidence of root caries in compromised adults (15–17). The prevalence of root caries is incidentally higher in elderly adults living in community-based residences or those diagnosed with dementia (17).

Most studies evaluating the effectiveness of fluoridated toothpastes have been conducted either in children or adolescents. The beneficial effect of high-fluoride toothpaste on dentin has already been demonstrated in vitro, preventing both mineral loss and lesion depth (18). A randomized control trial including adult dental school patients recruited with at least one root caries lesions has shown that high-fluoride toothpaste with 5000 ppm F was superior to a regular 1100-ppm F tooth gel (19). While another study has demonstrated that even regular toothpaste containing 1450 ppm F was beneficial in arresting root caries lesions (20). The elderly patients in this study however suffered from limited saliva function, although saliva secretion level had only poor predictive values for the preventive effect of the outcome. So there is still limited evidence about the superior effect of high-fluoride concentrations on arresting existing initial root caries lesions in an adult population.

The purpose of this clinical trial was to test the effectiveness of high-fluoride toothpaste (5000 ppm F) on root caries lesions in adults and to test the hypothesis that high concentration fluoride toothpaste would effectively improve the surface hardness in root caries lesions in adult patients.

**Methods**

**Trial design**
This single-blind, multicenter, parallel, randomized controlled trial with an allocation ratio of 1:1 was approved by the ethics committee of the University of Cologne in Germany (Approval No. 04–113), and notified with the BfArM (German Drug Regulatory Agency, Bonn, Germany). No modifications to the trial methods were performed after trial commencement. This randomized controlled trial is reported in accordance with the CONSORT (Consolidated Statement Of Reporting Trials) statement (21).

**Participants**
Adult patients, diagnosed with untreated root caries, were to be included in the trial. The eligibility criteria for the recruitment of the study cohort are listed in Table 1. This trial was conducted under university settings, and participants were recruited from the patient clinics of three dental schools located in Cologne (Germany), Leipzig (Germany) and Geneva (Switzerland).

**Table 1. Predefined inclusion and exclusion criteria for the recruitment of subjects**

| Inclusion criteria | Exclusion criteria |
|--------------------|-------------------|
| Age group between 18–75 years | Medically unfit, or the presence of any hard or soft tissue tumors in the oral cavity |
| Must have 10 or more natural teeth | Patients undergoing radiation therapy |
| Must have at least one root caries lesion | Ongoing fixed orthodontic appliance therapy |
| Teeth included in the study must not be crowned or compromised | Open or active coronal decay |
| Not having participated in another clinical trial in 6 months prior to this trial | Undergone high-fluoride therapy 6 months prior to this trial |
| | Local or systemic antibiotic therapy within the 6 months |
| | Pregnancy, lactating, or hypersensitive to the trial test products |
| | Acute progressive periodontitis |
Interventions
The patients were distributed in two groups (test and control groups). The patients in the test group were administered with toothpastes containing high-fluoride of 1.1% sodium fluoride (Duraphat 5000 ppm F; Colgate–Palmolive Company, Hamburg, Germany) in a silica substrate. The control group participants were allotted with standard regular-fluoride toothpaste (Odol-med 3, 1350 ppm F; GlaxoSmithKline, Brühl, Germany). Interventions were dispensed in separate packets to each patient according to their allotted groups. The packets were identical and consisted of three or four tubes of toothpastes along with two standard soft bristled adult toothbrushes.

Outcome measures
The primary outcome measure determining the effectiveness of the test toothpaste was to evaluate the changes in the surface structure of the root caries lesions after the intervention. The following linear clinical surface texture grading scale was adopted for the evaluation of root caries surface hardness as validated in a former study (22):
- Level 1: Hard
- Level 2: Hard to Leathery
- Level 3: Leathery
- Level 4: Leathery with local softening
- Level 5: Soft

The surface hardness scores (HS) were recorded at:
- Baseline ($T_0$),
- 3 months after intervention ($T_1$), and
- 6 months after intervention ($T_2$).

There were no changes to the outcome measures after trial commencement.

Sample size
The sample size calculation was based on the findings from similar studies published in the literature (19, 23). The desired statistical power was set at 80% ($1 - \beta = 0.8$) at a significance level of 5% ($\alpha < 0.05$). Ninety subjects per group were required to avoid any statistical type II errors.

Randomization and blinding
The random allocation sequence was generated manually in the Medical Research Department at Colgate–Palmolive Company in Hamburg, Germany. A block randomization was carried out (block size = 10; allocation ratio = 1:1). The randomly allocated sequence was implemented and concealed in sequentially numbered, consecutive, nontransparent sealed envelopes. The envelopes were maintained in the possession of each center’s chief investigator. The envelopes were opened only prior to intervention after patient enrollment and after receiving the patient’s consent. A single investigator from the medical research department at Colgate, who was not involved in the participants’ enrollment process, generated the random allocation sequence. Consecutive patients who fulfilled the inclusion criteria were enrolled in the trial in each of the three centers. The examiners recruited the participants and were blinded to the participants’ group allotments.

Statistical methods
Statistical analyses were performed on a subject level and not on a surface level (24, 25). The mean HS was calculated for each subject by dividing the sum of individual surface scores by the number of surfaces scored. This mean HS was recorded for $T_0$, $T_1$ and $T_2$. The test and the control groups were compared at baseline in regard to age (unpaired $t$-test), gender (chi-squared test), and initial HS-score (unpaired $t$-test). Homogeneity of variances between groups was verified using F-tests ($0.079 < P < 0.8757$). Subsequently, a two-way analysis of variance (ANOVA) was performed to compare the HS scores of the two groups; with ‘group’ and ‘time point’ as independent variable. The interaction term was calculated and a post hoc Bonferroni–Dunn comparison with correction for repeated measures was performed. The level of significance was set to $P < 0.05$. For the statistical analysis, SPSS 16.0 for Windows (SPSS Inc., Chicago, IL, USA) and StatView 5.0 for Windows (SAS Institute Inc., Cary, NC, USA) were used.

Study protocol
A training meeting was conducted in Cologne for all the examiners in order to calibrate them to the patient recruitment and examination procedures, clinical scoring of the root surfaces, and data extraction procedures. Interoperator and intraoperator reliability was assured during this training session, and the applied probing pressure was also standardized. The interexaminer agreement of the clinical root caries scale was determined during the calibration meeting in Cologne where 19 patients were examined by all investigators. The unweighted kappa value was 0.84. Consecutive patients in each center qualifying based on the inclusion and exclusion criteria were screened and included in the study. After the initial review and
examination, the patients were given detailed written information about the trial and a signed written consent was obtained from each patient who participated in the study. Baseline clinical examinations, including a complete oral health check-up, caries status, and plaque index were performed for all participants (Loe and Silness) (26). The surface hardness for the root caries lesions was graded and recorded with a standardized dental probe. This probe was standardized by type, model, and brand (Pluradent 43124 lot 20774; Offenbach, Germany), to be used for this study in all the three centers. A complete full mouth oral prophylaxis was performed, and oral hygiene instructions were given prior to the start of the study. The patients were then instructed on the use of the test products. Instructions were given to replace the toothbrushes provided every 6 weeks and were replaced with the same type of soft brushes as provided at the start of the study. During the study period, the patients received the same intervention packets every 3 months. Unused products were to be returned to the respective investigator during the examination visits at 3 and 6 months.

During the trial period, the patients were given specific instructions on brushing, that is, twice daily for 2 minutes with the toothbrushes and pastes provided. The quantity of the toothpaste to be used for each brushing procedure was approximated to about 1 g. Patients were strictly instructed to refrain from using toothpastes or toothbrushes other than the ones provided to them. They were also restricted from using mouth rinses. In contrast, no restrictions were made on the use of dental floss, interdental aids or denture cleansers during the trial period. No changes were recommended in their habits of smoking or diets during the study period. Patients were asked questions on their oral hygiene habits and were requested to fill in a final questionnaire at the end of the trial.

**Results**

A total of 142 patients were assessed for eligibility by the three participating centers. Seven patients were excluded and finally 135 patients (test group: \( n = 67 \); control group: \( n = 68 \)) with 318 identified root caries lesions (L) were randomized and enrolled in the trial to receive the intended interventions. After trial commencement, five patients (test group: \( n = 3 \); control group: \( n = 2 \)) were excluded from the study because they were lost to follow-up. Hence, a total of 130 patients (test group: \( n = 64, \text{L} = 144 \); control group: \( n = 66, \text{L} = 160 \)) were included in the final analysis for the primary outcome measure. The CONSORT flow diagram of the phases in the participant recruitment, randomization, follow-up and analysis is presented (Fig. 1). Recall examinations were performed at 3 (\( T_1 \)) and 6 months (\( T_2 \)) after intervention. The trial concluded after all the patients were examined at \( T_2 \), as originally intended in the original protocol.

The relevant patient demographics, group allocation and observations at \( T_0 \) are presented.
Impact of high-fluoride toothpaste on root caries

Table 2. Baseline demographics of the study groups

| Test group | Control group |
|------------|---------------|
| Test center | Subjects (n) | Mean age (years) | Mean HS | Subjects (n) | Mean age (years) | Mean HS |
| Cologne    | M | F | T | 62.6 ± 8.3 | 3.5 ± 0.51 | 62.2 ± 8.6 | 3.5 ± 0.51 |
| Leipzig    | 8 | 9 | 17 | 60.3 ± 10.9 | 3.5 ± 0.50 | 55.9 ± 10.7 | 3.5 ± 0.59 |
| Geneva     | 13 | 5 | 18 | 51.8 ± 15.4 | 3.1 ± 0.75 | 43.1 ± 14.0 | 3.2 ± 0.89 |
| Total      | 37** | 27** | 64 | 59.0 ± 12.1† | 3.4 ± 0.61*** | 54.8 ± 13.5† | 3.4 ± 0.66*** |

Test Group, High-fluoride toothpaste (5000 ppm F); Control Group, Regular-fluoride toothpaste (1350 ppm F); n, Number; M, Male; F, Female; T, Total; HS, Surface hardness score.

P = 0.0682 (unpaired t-test); **P = 0.9786 (chi-squared test); ***P = 0.8757 (unpaired t-test).

(Table 2). At T₀, the two groups were not different with respect to age (P = 0.0682, unpaired t-test), gender (P = 0.9786, chi-squared test) and baseline mean HS values (P = 0.8757, unpaired t-test).

Root caries surface hardness analysis

The changes in the HS for each of the individual study center are tabulated in Table 3. The statistical model revealed a significant effect of the tested intervention (P = 0.009, ANOVA) and time (P < 0.0001, ANOVA) on the mean HS (Table 4). However, the interaction term was not significant (group*time-point: P = 0.1151, ANOVA) as the HS improved within both the test and the control groups (P < 0.0001, ANOVA, T). The post hoc analysis (adjusted P-value for significance according to the Bonferroni–Dunn correction: P = 0.0167) revealed that HS scores between the test and control groups were significantly different at the end of the observation period [P = 0.0067(S), Bonferroni–Dunn], but not at T₀ and T₁ (P = 0.8757 and P = 0.1787, respectively, Bonferroni–Dunn). Furthermore, HS scores improved significantly in the test group between all time points (T₀–T₁: P = 0.0008, T₁–T₂: P < 0.0001, Bonferroni–Dunn). In the control group, the HS improved only after 3 months into the study (T₀–T₁: P = 0.0358; T₁–T₂: P < 0.0122; P-value: Bonferroni–Dunn).

Discussion

Although the methodology followed in this study protocol is robust, a few limitations do exist. Due to technical reasons, it was not possible to produce identical packages for the test and control toothpaste. Consequently, the patients knew whether they were in the test or in the control group even though they were supposed to be blinded to the interventions. However, the examiner was blinded to the patient’s group assignment. Another shortcoming was the failure to recruit the sample size proposed by the power calculation (27). The power was not adequate to demonstrate that the high-fluoride group improved surface hardness better than the low-fluoride group over time. This may have been better demonstrated with a larger sample size. However, a surface level analysis could have been performed in this study to increase the power of the study. This was not performed because surface level data cannot be considered as independent observations. Nevertheless, the sample size of the current study was sufficient to demonstrate a significant difference between the interventions groups without taking the time point into consideration. The duration of this clinical study was limited by expiry date of the test product, and these products were all provided immediately after ethical approval. Hence, the recruitment process was thus shortened and consequently, smaller than intended sample size. Despite a carefully planned calibration meeting, differences might have occurred between the study centers in performing the protocol or in the features of the enrolled patients and therefore in the results obtained. However, these differences did not preclude the significant differences between the test and control groups after an observation period of 6 months. Due to our stringent patient selection criteria resulting in the exclusion of compromised individuals, the generalizability of the results may be limited.

Numerous studies are present in current literature, which highlight the benefits of using fluoridated dentifrices in the prevention and treatment for dental caries in children and young adults (11, 28–30). Very few studies have focused on the potential benefits of using fluoridated toothpastes in adults, more specifically the compromised elderly adults, and even fewer studies have vali-
Table 3. Changes observed in the mean surface hardness scores in the individual study centers

|             | Cologne | Leipzig | Geneva |
|-------------|---------|---------|--------|
|             | Test group | Control group | Intergroup comparison<sup>a</sup> | Test group | Control group | Intergroup comparison<sup>a</sup> | Test group | Control group | Intergroup comparison<sup>a</sup> |
| Observation time |       |         |       |       |         |       |       |       |       |
| T<sub>0</sub> | 3.5 ± 0.51 | 3.5 ± 0.51 | P = 0.8987 | 3.5 ± 0.50 | 3.5 ± 0.59 | P = 0.8486 | 3.1 ± 0.75 | 3.2 ± 0.89 | P = 0.7695 |
| T<sub>1</sub> | 2.8 ± 0.56 | 3.7 ± 0.60 | P = 0.0764 | 3.2 ± 0.69 | 3.3 ± 0.60 | P = 0.4447 | 3.1 ± 0.80 | 3.1 ± 1.02 | P = 0.3211 |
| T<sub>2</sub> | 2.0 ± 0.57 | 2.7 ± 0.67 | P < 0.0001 | 2.7 ± 0.65 | 2.7 ± 0.65 | P = 0.2226 | 2.5 ± 0.91 | 3.0 ± 1.08 | P = 0.1610 |
| Intragroup comparison<sup>a</sup> |       |         |       |       |         |       |       |       |       |
| T<sub>0</sub> versus T<sub>1</sub> | P < 0.0001 | P = 0.0899 |       | P = 0.3693 | P = 0.1484 |       | P = 0.4212 | P = 0.9921 |       |
| T<sub>0</sub> versus T<sub>2</sub> | P < 0.0001 | P < 0.0001 |       | P = 0.0134 | P = 0.0010 |       | P = 0.0654 | P = 0.6816 |       |
| T<sub>1</sub> versus T<sub>2</sub> | P < 0.0001 | P < 0.0001 |       | P = 0.0161 | P = 0.0492 |       | P = 0.2886 | P = 0.6889 |       |

Test Group, High-fluoride toothpaste (5000 ppm F); Control Group, Regular-fluoride toothpaste (1350 ppm F); T<sub>0</sub>, Baseline; T<sub>1</sub>, 3 months; T<sub>2</sub>, 6 months.

<sup>a</sup>Post hoc Bonferroni–Dunn correction for multiple comparisons, adjusted P-value for significance P = 0.0167.
Conclusions
The application of a high-fluoride containing dentifrice (5000 ppm F) in adults, twice daily, significantly improves the surface hardness of untreated root caries lesions when compared with the use of regular fluoride containing (1350 ppm F) toothpastes. The potential application of such a product is particularly beneficial in improving oral health and reducing root caries susceptibility in elderly adults.

Acknowledgements
The authors’ institutions received per capita remuneration and the products used in this clinical trial, from Colgate – Palmolive Company. Roger P. Ellwood and Michael Warncke are employees of the Colgate – Palmolive Company.

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