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The effect of a modified fluoride toothpaste technique on buccal enamel caries in adults with high caries prevalence: a 2-year clinical trial

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Objective: To evaluate the preventive effect of a "modified fluoride (F) toothpaste technique" on the incidence and progression of buccal/lingual enamel caries among Saudi adults with high caries prevalence. ***Method:*** Adults were randomly assigned to test and control groups. Test group patients were instructed to use the provided F toothpaste twice a day as follows: 1, use 2cm toothpaste; 2, brush for 2min; 3, swish the toothpaste slurry around the teeth for about half a minute before spitting it out; and 4, no post-brushing water rinsing and no eating/drinking for 2hr. The patients in the control group (n=57) were instructed to continue using their regular F toothpaste twice a day without any further instructions. The patients' compliance in the test group was assessed after 2 years. ***Results:*** Of 175 adults, 113 completed the study. The test group (n=56) had a lower enamel mean caries incidence 0.56 (sd 1.04) than the control group (n=57), 1.01 (1.00) ($p<0.05$), with a preventive fraction of 44%. There was no difference regarding enamel caries progression or arrested caries. The caries incidence in the test group was higher in the subgroup of patients who rinsed with water post-brushing and who only brushed once a day ($p<0.05$). ***Conclusion:*** The "modified fluoride toothpaste technique", as practised over the 2 years in a Saudi population with high caries prevalence, had a preventive effect on the incidence of buccal/lingual enamel caries but not on the progression.

Key words: *adults, dental restorations, enamel caries, fluoride toothpaste, Saudi Arabia.*

Introduction

The decline in dental caries prevalence in developed countries over the last four decades is mainly due to the widespread use of fluoride (F) toothpaste (Marinho *et al*., 2003). In contrast, the high level of caries in developing countries nowadays is largely due to less exposure to F, in addition to other risk factors, such as high sugar intake.

Toothpaste is the most common vehicle for delivering F topically. However, many behavioural factors could influence its efficacy in caries prevention (Davies *et al*., 2003) including the frequency of brushing, the amount of toothpaste applied and the post-brushing water rinsing. All these factors might affect the availability of F in saliva and dental plaque. It has been reported that caries increments in individuals who brush only once a day were 20-30% higher than in those who brushed twice a day (O'Mullane *et al*., 1997). Furthermore, the mean F level in saliva after brushing with a small amount of toothpaste (~0.25 g) was approximately one third of that obtained with a normal amount (~1.0 g) (DenBesten and Ko, 1996). Another interesting factor is the post-brushing rinsing behaviour. Individuals who rinse with large volumes of water have higher caries incidence than those who rinse with smaller volumes (Chestnutt *et al*., 1998, O'Mullane *et al*., 1997).

In a previous study, the approximal caries in Swedish preschool children was reduced by an average of 26% after using the so-called "modified toothpaste technique" (Sjögren *et al*., 1995). They were instructed to swish the toothpaste foam, together with a sip of water (approximately 10 ml), around the dentition by active cheek movements, before spitting it out. In a recent study carried out by our research group, this technique reduced approximal caries by 66% in an adult Saudi population (Sonbul and Birkhed, 2010). The hypothesis of the present study was that standardising several factors involved in the behaviour of using F toothpaste, here called the "modified fluoride toothpaste technique", would improve the effects of F toothpaste. The aim of the present trial was therefore to evaluate the preventive effect of the "modified fluoride toothpaste technique" on the incidence and progression of buccal/lingual enamel caries in an adult Saudi population with high caries prevalence.

Method

All adult patients visiting the Emergency Dental Clinic at the Faculty of Dentistry, King Abdulaziz University, Jeddah, and the Dental Health Clinic of Internal Security, Makkah, Saudi Arabia, from February to May 2006, were clinically screened using the criteria: at least 20 teeth; at least 7 teeth with dental restorations; and willingness to participate in the study. Of the 511 patients screened, 175 fulfilled all three criteria and were included in the study. The caries prevalence and risk profile of this population have been reported as high (Sonbul *et al*., 2008). The F level in water is low (0.22 mg F/L) (Rugg-Gunn *et al*., 1997).

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Patients were assigned to test and control groups according to a pre-randomised list. Informed consent was obtained and the local ethics committee had approved the study (code number 29/1/1419).

At the start of the study, patients in the test group were instructed to use F toothpaste twice a day, with the "modified fluoride toothpaste technique" as described by Sjögren *et al*. (1995) though the amount of toothpaste used was 2cm (~1 g) instead of 1cm and the post-brushing rinsing with water was omitted. The technique can therefore be summarised in 4 steps: squeeze 2cm of the toothpaste over wet toothbrush bristles; brush for about 2min and do not to spit out more than necessary during brushing; after brushing, swish the remaining toothpaste foam and saliva, here called "slurry", around the teeth with active movements of the cheeks, lips and tongue, forcing the slurry in between the teeth for about half a minute before spitting it out; and finally, no post-brushing water rinsing and no eating/drinking for at least 2hr post-brushing. To clarify these steps, they were described in a set of coloured photographs, in a pamphlet given to patients.

The F toothpaste used by patients in the test group was Colgate Maximum Cavity Protection (Colgate, Piscataway, USA), with 1450 ppm F, is a commonly available in Saudi Arabia. Patients in the control group were instructed to continue using their regular F toothpaste (all 1450 ppm F and identified prior to the trial) twice a day without any further instructions. At the start of the trial, 7 patients in the control group, who never used any F toothpastes, were given Colgate Maximum Cavity Protection F toothpaste.

Throughout the 2-year period, the patients in the test group were recalled every 6 months to be reminded about the "modified fluoride toothpaste technique". Instructions were reinforced while the patient was performing the technique and the coloured pamphlet was given again at the end of the session. Four 120ml tubes of the toothpaste were distributed on each recall visit.

At the end of the trial and after plaque and caries registration, the patients in the test group were monitored by a well-trained dental assistant, while performing the technique, and their compliance was assessed. The amount of toothpaste, the brushing time and the post-rinsing behaviour were noted. In addition, the patients were interviewed regarding the regular use of F toothpaste, frequency of brushing and refraining from eating/drinking for 2hr. According to the data collected, the patients in the test group were divided into 2 subgroups, here called A and B. The patients who had followed the four steps in principle were scored as A, while those who brushed their teeth once per day and/or rinsed with a sip of water post-brushing were scored as B.

Patients in the control group were also recalled every 6 months. On each of these visits, the use of F toothpaste twice a day was emphasised and a toothbrush was given to each patient (but not to the test group). The regular use of F toothpaste and the frequency of brushing during the 2 years were assessed in the control group by interviewing the patients at the end of the study.

Before the start of the study and after the 2 years, the plaque index was recorded for all patients according to Silness and Löe (1964). A probe was used to validate the presence of plaque. Four surfaces were examined on each of the following teeth: 16, 12, 24, 36, 32 and 44. Clinical examination were carried out at baseline and after 2 years by one of the authors (HS), using magnification glasses (x2.5), a dental mirror and with the patient seated in a dental chair under optimal light. All buccal and lingual surfaces were examined for non-cavitated lesions, here called "enamel caries". The surfaces were cleaned carefully with cotton rolls and dried with compressed air, before caries registration. The caries diagnostic criteria used in the present study were modified from Nyvad *et al* (1999); only scores for the non-cavitated lesions were used (Table 1). Surfaces with restorations were recorded as filled (FS). Enamel lesions (DiS) were scored with regard to surface integrity (intact or discontinuity in enamel) and whether they were active or inactive (the latter was called "arrested caries"). A combination of visual and tactile criteria was used to differentiate between active and arrested caries lesions. The probes were used gently to check for surface integrity. Surfaces with mixed carious lesions were scored according to the one that was most severe. For intra-examiner reliability, 408 surfaces in eight patients were re-scored after two weeks; the kappa value was 0.81.

Table 1. Description of the diagnostic criteria (after Nyvad *et al*., 1999)

Score	*Category*	*Criteria*
0	Sound	Normal enamel translucency and texture.
1	Intact surface (active caries)	Surface of enamel is whitish/yellowish opaque with a loss of lustre; feels rough when the tip of the probe is moved gently across the surface; generally covered with plaque. No clinically detectable loss of substance. Caries lesion typically located close to gingival margin.
2	Surface discontinuity (active caries)	Same criteria as score 1. Localised surface defect (microcavity) in enamel only.
3	Intact surface (inactive caries)	Surface of enamel is whitish, brownish or black. Enamel may be shiny and feels hard and smooth when the tip of the probe is moved gently across the surface. No clinically detectable loss of substance. Caries lesion typically located at some distance from gingival margin.
4	Surface discontinuity (inactive caries)	Same criteria as score 3. Localised surface defect (microcavity) in enamel only.
5	Cavity	Dentine cavity easily visible to the naked eye.
6	Filling	Sound enamel and dentine around filling.
7	Recurrent caries	Decalcification and/or frank caries is visible around the filling.

After 2 years, the count of all the sound surfaces at baseline that had developed enamel caries lesions (DiS), cavitated lesions (here called "manifest caries" DmS) or had been filled (FS) was defined as "total caries incidence", i.e. 0>1-6. A change from the baseline score from 1>2, 4 or 5, or from 2, 3 or 4>5, was defined as "progressed enamel caries". All enamel caries lesions that had been filled, i.e. 1, 2, 3 or 4>6, were registered. Only decalcification and/or frank carious lesions at the margin of the restoration were registered as recurrent caries (DrecS); marginal staining was therefore excluded. The summation of all the aforementioned events was defined as "total caries progression". Furthermore, all changes from 1 or 2 to 3 or 4 were collectively referred to as "arrested caries".

The dental assistant handled all the data collection relating to the interview and compliance, including the group assignment, which was kept unavailable to the examiner.

Data were analysed using the SPSS statistical package (v17.0, SPSS). The mean and standard deviation of caries prevalence (DFS), located buccally and lingually, were calculated for both groups at baseline. Student's t-test was used to compare groups with regard to total caries incidence, total caries progression and arrested caries, while a paired t-test was used to compare the mean of plaque scores. The Mann-Whitney U test was performed to compare the compliance in the test group regarding total caries incidence and progression. Significance tests were performed at individual (not site) level and differences giving a $p<0.05$ were considered significant. A power analysis with an assumption significance level of 5%, a standard deviation of 3.0 and a power of 90% to detect at least 2 differences gave a sample size of 48 individuals per group.

Results

Of the 175 participants, drop-outs after 2 years totalled 62 leaving 113 patients completing the trial: 56 in the test group, 57 in the control group. The reasons for drop-outs are given in Table 2. In the test and control groups, 15 and 17 patients respectively quit the study. Unwillingness to continue was the main reason in both groups and mean baseline DFS of those retained was similar between groups. Based on the interview data, all the patients in the test and control group used the F toothpaste regularly during the entire trial. The plaque score had improved after 2 years in both groups ($p<0.01$) (Table 3). At the end of the study, around 92% of the patients in both groups claimed they brushed their teeth twice daily using F toothpaste.

Table 4 presents the total caries incidence, total caries progression and arrested caries after 2 years. Most of the enamel caries was located on the buccal surfaces (~97%). A significant difference was found when comparing the total caries incidence in the test group, mean 0.57 (sd 1.04), and the control group, 1.01 (1.00) ($p<0.05$). The preventive fraction (difference in incidence between groups / incidence in control group) was therefore ~44%. At the end of the study, the mean number of enamel caries that had been filled (FS) in the test and control groups was 1.63 (sd 1.60) and 1.75 (1.35) respectively. The diagnosed recurrent caries (DrecS) was 0.43 (1.22) and 0.72 (1.58) in the test and control groups respectively (data not shown).

Based on the compliance assessment, the total caries incidence was lower in (high compliance) subgroup A (n=43), 0.37 (0.75), than in subgroup B (n=13), 1.23 (1.54) ($p < 0.05$).

Table 2. Number of patients included in the study (n=175), drop-outs and number of scored buccal/lingual surfaces together with the baseline characteristics of patients who completed the 2-year trial (n=113)

	Test	*Control*	*All*
Number of patients:			
Start of the study	88	87	175
Drop-outs	32	30	62
Reasons for drop-outs:			
Could not be reached or left the city	17	13	30
Quit the study	15	17	32
Retained to end of the study (after 2 years)	56	57	113
Baseline characteristics, mean (sd)			
Total number of months for the whole study	24 (1.0)	24 (1.6)	24 (1.4)
Age in years	30 (10.2)	27 (8.4)	29 (9.5)
Gender			
Female	43	41	84
Male	13	16	29
DFS	36.5 (14.7)	34.6 (14.9)	35.5 (14.8)
Number of teeth	25 (2.2)	26 (2.1)	26 (2.1)
Number of scored surfaces per patient	50.9 (4.4)	51.8 (4.2)	51.3 (4.3)
Total number of scored surfaces	2848	2952	5800

Table 3. Number of patients using F toothpaste and their frequency of brushing and plaque scores at baseline and after 2 years for both the test and control groups

	Test n=56		Control n=57		Total n=113	
	Baseline	2-year	Baseline	2-year	Baseline	2-year
Number of patients:						
using F toothpaste	46	56	50	57	96	113
not using F toothpaste	10	0	7	0	17	0
Frequency of brushing:						
now and then	15	0	18	0	33	0
once per day	16	5	13	4	29	9
twice per day	15	51	19	53	34	104
Plaque index, mean (sd)	1.2 (0.5)	** 1.0 (0.5)	1.3 (0.4)	** 1.1 (0.3)	1.3 (0.5)	** 1.1 (0.4)

** $p<0.01$

Table 4. Mean (sd) of the total enamel caries incidence, total progression and arrested lesions for the patients in the test and control groups after 2 years

	Test, n=56	*Control, n=57*	*p-value*
Total caries incidence	0.57 (1.04)	1.01 (1.00)	*<0.05*
Total caries progression	2.77 (2.91)	3.30 (2.46)	
Arrested caries (active>inactive)	1.32 (1.18)	0.96 (1.15)	

The total caries incidence includes 0>1-6, while all progressed lesions, new filled surfaces and recurrent caries were collectively used to indicate the total progression.

Discussion

The result of the present 2-year clinical study of an adult Saudi population with high caries prevalence revealed that the "modified fluoride toothpaste technique" had a preventive fraction of around 44% on buccal/lingual enamel caries. A previous study of the same population used the same technique and revealed a reduction of 66% in approximal caries, scored on bitewing radiographs (Sonbul and Birkhed, 2010).

The difference in caries incidence between the test and control group could be due to many factors. One could be the prolonged availability of a high level of F in the test group, as a result of refraining from post-brushing water rinsing. This improves the chance of F being incorporated into the enamel and dentine, thereby rendering the surface more resistant to acidic challenge (ten Cate, 1999). By avoiding water rinsing, particularly in adults, the salivary F level can remain high up to 2hr post-brushing (Issa and Toumba, 2004). Furthermore, Sjögren and Birkhed (1993) reported that adult patients with high caries activity rinsed with water after brushing more frequently than those with low caries activity. This was supported in the present study, as the caries reduction in subgroup A (with good compliance) was approximately three times higher than that in subgroup B (less good compliance). This is also in agreement with several reports that have shown an association between caries incidence and frequency of brushing and post-brushing behaviour (Chestnutt *et al*., 1998, O'Mullane *et al*., 1997). There is, however, some controversy regarding the effect of post-brushing water rinsing *per se* on caries development. The difference between the mean caries increments with and without rinsing was only 0.8 DS in a longitudinal clinical trial and not statistically significant (Machiulskiene *et al*., 2002). In that study, however, the population was not made up of caries-prone individuals, as in the present trial. In addition, it was not stated if the children were instructed not to eat or drink post-brushing. This might be an important factor when it comes to maintaining a high F level in the oral cavity after refraining from water rinsing. Sjögren and Birkhed (1994) found that eating/drinking directly after brushing reduced the F concentration considerably.

The amount of F that might be swallowed as a result of the "modified F toothpaste technique" is less critical in an adult than with a child. Up to 20% of toothpaste was swallowed when no water rinsing took place post-brushing (Sjögren *et al*., 1994). This corresponds to 0.3 mg F/brushing, when using 1 g of toothpaste with 1500 ppm F. This amount corresponds to one cup of tea (~1 dL) containing 3 mg F/L. From a toxicological point of view, this is considered to be negligible for an adult.

The recall visits every 6 months probably played a major role in improving the oral hygiene of the patients in both groups. The plaque reduction was more or less the same in the test and control group. Nevertheless, the enamel caries incidence on the buccal/lingual surfaces was lower in the test group than the control group. It is therefore possible to conclude that the "modified fluoride toothpaste technique" was the main factor contributing to the caries reduction in the present study. Another in-

teresting observation in the present trial was that most patients (77%) in the test group did comply with the instructions. The technique was therefore easy for adults to adopt. The most common complaint from the patients who wanted to rinse with a sip of water was that they could not get used to the strong taste of the toothpaste slurry that was left after brushing.

The "modified fluoride toothpaste technique" did not show a pronounced effect on enamel caries progression, compared with the development of new lesions. Although the presence of F enhances the remineralisation process, it has been shown that the effect is more apparent in the demineralisation of enamel rather than the remineralisation (ten Cate *et al*., 1995). Furthermore, the depth of the lesions could also influence the efficacy of F toothpaste (ten Cate *et al*., 2006). In our study, the clinical examination of the enamel caries was dependent on visual and tactile criteria, not on depth. Consequently, methods that measure the depth of the lesions should be used in order better to evaluate the possible effect of the "modified F toothpaste technique" on remineralisation. The number of arrested enamel caries surfaces was similar in both groups. This could be attributed to the fact that the buccal enamel caries is accessible to the mechanical action of the toothbrush bristles that might lead to the abrasion of the superficial layer of the lesion. An effect of this kind has been reported in clinical studies (Årtun and Thylstrup, 1989; Holmen *et al*., 1987). Surprisingly, we have found that many enamel caries were filled at the end of the trial. This somewhat "aggressive" approach towards operative intervention should be discouraged and replaced by promoting the preventive management of enamel caries, including the use of F toothpaste, and pursuing caries risk assessment.

In conclusion, the "modified fluoride toothpaste technique" had a preventive effect on the incidence of buccal/lingual enamel caries in adult Saudis with high caries prevalence. The good compliance in the majority of the patients indicates that the technique is easy for adults to adopt and is therefore useful in caries prevention at community level.

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