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ORIGINAL ARTICLE

The clinical comparison of a triclosan/copolymer/fluoride dentifrice *vs* a breath-freshening dentifrice in reducing breath odor overnight: a crossover study

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OBJECTIVE: The objective of this randomized, crossover study was to compare the effectiveness of the triclosan/copolymer/sodium fluoride (TCF-AF) dentifrice and a commercially available breath-freshening dentifrice containing fluoride for their ability to reduce volatile sulfur compounds (VSC) associated with oral malodor overnight.

METHODS: Following a 1-week washout period of brushing with a regular fluoride dentifrice, subjects reported to the clinical site without performing oral hygiene, eating or drinking in preparation for baseline breath sampling. Subjects were randomly assigned a test dentifrice and instructed to brush their teeth for 1 min, twice a day for 1 week. On the morning of day 8, subjects returned to the test site, having refrained from oral hygiene, eating and drinking, for overnight sampling. Following a second 1-week washout period, subjects repeated the same regimen, but now using the other test product. At each measurement, the level of breath VSC was evaluated using a gas chromatograph equipped with a flame photometric detector. Measurements were taken in duplicate, and then averaged. The levels of VSC were expressed as parts per billion (ppb) in mouth air.

RESULTS: At baseline, the mean breath VSC levels for the TCF-AF and breath-freshening dentifrice were 618 and 581 ppb respectively. There was no statistically significant difference between the baseline levels. Overnight, the TCF-AF and the breath-freshening dentifrice reduced breath mean VSC levels to 267 and 521 ppb respectively. This gave a 56.7 and 10.2% reduction in VSC levels for these two products, respectively, compared with baseline. The reduction for the TCF-AF dentifrice was significantly different ($P < 0.05\%$) from that of the breath-freshening dentifrice.

CONCLUSION: The results of this randomized, double-blind, crossover study indicate that the TCF-AF dentifrice was significantly more effective than a commercially available breath-freshening dentifrice containing fluoride in reducing breath VSC associated with bad breath overnight.

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Keywords: triclosan/copolymer dentifrice; fluoride; fresh breath; gas chromatography; oral malodor; volatile sulfur compounds

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Introduction

The objective of this randomized, crossover study was to compare the effectiveness of the triclosan/copolymer/sodium fluoride (TCF-AF) dentifrice and a breath-freshening dentifrice containing fluoride for their ability to reduce volatile sulfur compounds (VSC) associated with oral malodor overnight.

Methods

Products tested

Two commercially available toothpastes, one containing 0.3% triclosan, 2% copolymer and 0.243% sodium fluoride in a silica base (Colgate-Palmolive Company, New York, NY, USA) and the other containing 0.243% sodium fluoride in a silica base (Proctor & Gamble Company, Cincinnati, OH, USA), were evaluated.

Clinical procedure

Healthy adult male and female subjects, age 21–60 years with a VSC level >300 ppb who signed the informed consent form were entered into the study. The design was a randomized, multiple-use, crossover study.

On day 1 of the study, subjects reported to the clinical facility without eating, drinking or performing oral hygiene for baseline breath VSC evaluation. There, each subject's breath odor was evaluated using a Wasson–ECE custom-built breath sampling gas chromatography system equipped with a flame photometric detector (Agilent

Table 1 Summary of age and sex characteristics of the study participants

Product	*No. of subjects*			*Age range*
	Male	*Female*	*Total*	
TCF-AF	12	5	17	21–60
Commercially available breath-freshening dentifrice	12	5	17	21–60

Model # 6890 Gas Chromatograph Agilent Technologies, Palo Alto, CA, USA). This method was previously described by Tonzetich (1971) and later by Niles and Gaffar (1995). Subjects were provided with a soft-bristled adult toothbrush, and instructed to brush their teeth with the assigned dentifrice twice a day for 1 min. They used the product for a period of 7 days. On the evening of day 7, subjects were instructed to brush their teeth just prior to retiring to bed for the night. The following morning (day 8), subjects reported to the clinical site without eating, drinking or performing oral hygiene for their overnight evaluation. During a 7-day washout period, subjects used a basic fluoride dentifrice and repeated the same regimen now using the other dentifrice.

Upon arrival at the testing facility, subjects were instructed to keep their mouths closed for 10 min. A sampling tube was slid between the lips and back of the teeth. With the mouth closed, gas was pulled from the subject's mouth directly into the inlet of the gas chromatograph through the gas sampling loop, which was used to inject 2 ml of the sample into the column for analysis. Subjects were instructed to perform the Val-Salva maneuver during sampling to ensure air was removed only from the mouth and not through the nasal passages or from the lungs. The entire sampling and measurement process was performed in duplicate at each evaluation, and the resulting two scores were averaged. The duplicate samples were analyzed for three VSC gases (hydrogen sulfide, methyl mercaptan and dimethyl sulfide) commonly found in mouth air.

Statistical method

For both products, paired *t*-tests were performed to compare overnight VSC levels to baseline VSC levels. Analysis of covariance was performed on the overnight results, using the baseline as the covariate. Treatments were declared statistically and significantly different if $P \leq 0.05$.

Results

A summary of the age and sex characteristics of the subjects who participated in the study is presented in Table 1. The TCF-AF dentifrice reduced breath VSC from 618 to 267 ppb, representing a 57% reduction compared with baseline. However, the commercially available breath-freshening dentifrice reduced breath VSC from 581 to 521 ppb, representing a 10.1% reduction compared with baseline (Table 2). The TCF-AF dentifrice was statistically significantly ($P < 0.05$) better than the commercially available breath-freshening dentifrice in reducing breath VSC associated with bad breath overnight (Table 3).

Table 2 Mean overnight post-treatment VSC scores after brushing with Colgate® Total® Advanced Fresh™ Dentifrice and a commercially available fluoride dentifrice

Product	*N*	*Mean baseline VSC levels (ppb)*	*Mean overnight VSC levels (ppb)*	*% Reduction compared with baseline*
TCF-AF	17	618.1 ± 269.9	267.4 ± 139.8	57
Commercially available breath-freshening dentifrice	17	580.9 ± 264.6	521.4 ± 217.3	10

Table 3 Significance of reduction compared with the commercial breath-freshening dentifrice

Product	*Reduction of VSC levels from baseline (ppb)*	*Significance*[a]
TCF-AF	330.7	$P < 0.05$
Commercially available breath-freshening dentifrice	59.5	

[a]When the overnight breath VSC scores were compared, the TCF-AF dentifrice produced statistically significantly less breath VSC than the breath-freshening dentifrice.

Discussion

The copolymer in the TCF-AF formula has been shown to enhance the delivery and retention of the antibacterial agent triclosan to oral surfaces (Nabi *et al*, 1989; Gaffar *et al*, 1990, 1994). Additionally, the formula was demonstrated to control oral malodor as assessed by a panel of hedonic judges (Sharma *et al*, 1999; Hu *et al*, 2003). This double-blind crossover clinical study demonstrated

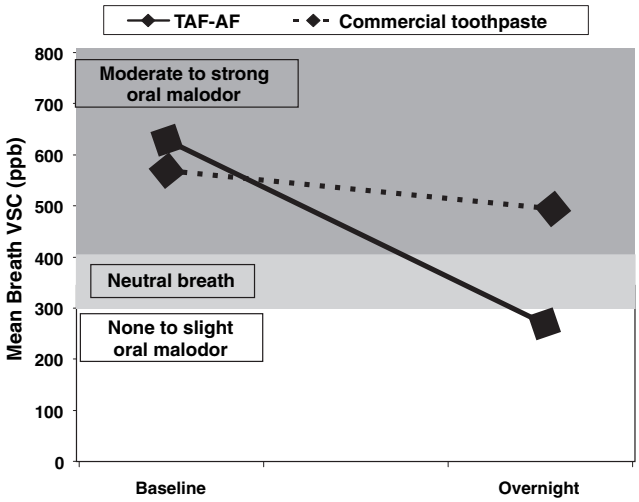

Figure 1 Comparison of overnight breath VSC after brushing the teeth

that a new variant of TCF-AF dentifrice, sold commercially as Colgate® Total® Advanced Fresh™ Gel, significantly reduced VSC associated with oral malodor overnight compared with baseline as well as a commercially available breath-freshening dentifrice. It was shown by Hunter *et al* (2003) that breath VSC levels below 300 ppb corresponded to subjects having no or slight oral malodor, while a breath VSC level above 400 ppb corresponded to subjects having moderate to strong oral malodor. The final mean overnight breath VSC level for the TCF-AF group was in the range corresponding to no or slight breath odor whereas, the final mean overnight breath VSC for the commercially available dentifrice was in the range corresponding to moderate to strong oral malodor (Figure 1).

The results of this randomized, double-blind, crossover study indicate that the TCF-AF dentifrice was significantly more effective than a commercially available breath-freshening dentifrice containing fluoride in reducing breath VSC responsible for bad breath overnight.

Acknowledgments

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Niles HP, Hunter CM, Vazquez J *et al* (2003). Clinical comparison of Colgate® Total® Advanced Fresh vs a commercially available fluoride breath-freshening toothpaste in reducing breath odor overnight: a multiple-use study. *Compend Contin Educ Dent* **24** (Suppl. 9): 29–33.

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