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The effect of a new toothpaste containing potassium nitrate and triclosan on gingival health, plaque formation and dentine hypersensitivity

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Abstract

Objectives: The purpose of this study was to investigate the effect of a new toothpaste containing an antiplaque and antiinflammatory agent (0.3% triclosan), a desensitizing agent (5% potassium nitrate) and an anticaries agent (0.76% sodium monofluorophosphate (SMFP)) on gingival health, plaque formation and dentine hypersensitivity in a 12-week home study. The efficacy of the test toothpaste was compared with that of a control toothpaste containing 5% potassium nitrate and 0.76% SMFP and a benchmark product containing only 0.76% SMFP.

Material and Methods: One hundred and two healthy volunteers, who had a minimum of 20 natural permanent teeth with no probing depth >4 mm and at least one sensitive tooth, participated in this study. Following enrollment, the subjects received a dental prophylaxis and instruction in brushing technique. After a 4-week pre-experimental phase, baseline gingival bleeding index (GBI), plaque index (PI) and visual analogue scales (VASs) indicating dentine hypersensitivity levels responding to tactile and air stimuli were assessed. The subjects were then randomly given one of the three toothpastes; test, control, or benchmark toothpaste, and a soft-filamented toothbrush for home use. The GBI, PI and VASs were re-examined at weeks 4 and 12.

Results: Overall, the GBI scores were significantly reduced compared with baseline in all groups ($p<0.01$). However, there was no significant difference in GBI score among the three comparison groups. The PI score decreased in the test group and benchmark group from baseline to the end of study, whereas there was no significant change in the control group. Post hoc comparison indicated that the PI score was not statistically different between the three groups. There was a significant difference between the three treatment groups for sensitivity. For both the tactile and air stimuli, the reductions in VAS sensitivity scores for the test group and the control group were significantly greater compared with the benchmark group. Although the sensitivity score for air stimulus decreased more rapidly from baseline to week 4 in the test group, there was no overall difference between the test group and the control group.

Conclusions: This study demonstrated that the new toothpaste was effective in reducing dentine hypersensitivity. More studies are needed to further determine the potential interaction between triclosan and potassium nitrate in dentifrices.

Key words: clinical trial; dentine hypersensitivity; fluoride; gingivitis; plaque; potassium nitrate; toothpaste; triclosan

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Dentine hypersensitivity is a common problem affecting between 8% and 57% of adult dentate population (Addy 1990, Irwin & McCusker 1997). It is associated with the exposure of dental root surfaces and is characterized by short, sharp pain in response to thermal, evaporative, tactile, chemical or osmotic stimuli, which cannot be ascribed to any other form of dental defect or pathology (Addy 1992, Holland et al. 1997). Most hypersensitive teeth are accompanied by gingival recession presumably resulting from periodontal disease, periodontal therapy, or improper brushing habits. Attempts to reduce dentine hypersensitivity have been aimed at either reducing the excitability of the nerve fibers within the pulp or occluding the open dentinal tubules. Various agents have been used as desensitizers for hypersensitive teeth including silver nitrate, fluoride, formaldehyde, strontium chloride and potassium nitrate (Kanouse & Ash 1969, Kanapka 1990, Trowbridge & Silver 1990, Orchardson & Gillam 2000). It is logical to incorporate these desensitizing agents into dentifrices that are typically used on a daily basis worldwide. Dentifrices containing potassium ions have been shown by several clinical studies to be effective in reducing dentine hypersensitivity and the American Dental Association Council on Dental Therapeutics has granted a Seal of Acceptance to dentifrices containing 5% potassium nitrate (Council on Dental Therapeutics 1986). Potassium ions are thought to act by blocking the action potential generated in intradental nerves (Markowitz et al. 1991, Peacock & Orchardson 1995).

The role of dental plaque in the etiology of periodontal disease has been well documented. Adequate self-performed mechanical plaque control is an important means to maintain periodontal health. However, in the average individual, compliance with toothbrushing tends to decrease and needs constant reinforcement. The addition of antiplaque/antimicrobial chemicals into toothpaste preparations have recently become a widespread approach aiming to improve the efficacy of self-performed mechanical tooth-cleaning procedures (Johansen et al. 1975, Bay & Rolla 1980, Etemadzadeh et al. 1985). Although chlorhexidine appears to be the most effective antiplaque agent, a significant reduction of its antiplaque potential may be observed when it is formulated into toothpaste (Gjermo & Rolla 1971, Barkvoll et al. 1989). In recent years, a number of clinical trials have suggested that toothpaste containing triclosan (2,4,4′- trichloro-2′-hydroxydiphenyl ether), a phenol-derived non-ionic antimicrobial agent, in combination with zinc salts or a copolymer may significantly interfere with the formation of supragingival plaque and hence provide an antigingivitis effect (Saxton et al. 1987, Svatun et al. 1987, 1989, Clerehugh et al. 1989, Garcia-Godoy et al. 1990, Lindhe et al. 1993, Palomo et al. 1994). In addition to its inhibitory effect on plaque formation, triclosan has been shown to have direct antiinflammatory properties (Barkvoll & Rolla 1994, Gaffar et al. 1995).

The purpose of this study was to investigate the effect of a new toothpaste containing 5% potassium nitrate and 0.3% triclosan on gingival health, plaque formation and dentine hypersensitivity in 12 weeks of home use. The efficacy of the new toothpaste was compared with that of a control toothpaste containing 5% potassium nitrate and a benchmark product that did not contain the two active agents. All of the toothpaste preparations in the present study included 0.76% sodium monofluorophosphate (SMFP).

Material and Methods

The protocol for human subjects was approved by the Khon Kaen University review committee. After informed consent was obtained, 102 healthy volunteers aged between 21 and 59 years, who satisfied the inclusion and exclusion criteria, participated in this study. To qualify for possible inclusion the subjects needed to have a minimum of 20 natural permanent teeth with no clinical attachment loss (CAL) greater than 5 mm and no probing depth >4 mm. In addition, the subjects had to have at least one tooth (either canines or premolars) with an exposed root surface from which a painful response could be elicited by both a dental explorer and air blast. Subjects were excluded from the study if they had any one of the following conditions: (1) a history of hypersensitivity to toothpaste, triclosan or chemicals used in the study products; (2) the use of antibiotic, antimicrobial, analgesic medications, mouthwash or desensitizing toothpaste during the previous 2 months; (3) a history of periodontal therapy by surgical interventions; (4) a history of dentine hypersensitivity treatment; (5) orthodontic treatment with fixed appliances; (6) any removable device such as a removable partial denture or orthodontic retainer; (7) the presence of any fixed appliance, large or defective restorations, cracked enamel, or caries on the hypersensitive tooth; (8) any smoking habits; (9) pregnancy or lactation.

The study was a randomized, double-blind, parallel group comparison of three toothpaste types:

(1) toothpaste containing 5% potassium nitrate, 0.3% triclosan and 0.76% SMFP (Sensodyne Fresh Mint with triclosan (new formula), GlaxoSmithKline (Thailand) Ltd, Bangkok, Thailand) (test group),
(2) toothpaste containing 5% potassium nitrate and 0.76% SMFP (Sensodyne Fresh Mint without triclosan (old formula), GlaxoSmithKline (Thailand) Ltd) (control group),
(3) toothpaste containing 0.76% SMFP (benchmark group).

Following enrollment, the subjects received a dental prophylaxis and instruction in brushing technique. After a 4-week pre-experimental phase, baseline gingival bleeding index (GBI), plaque index (PI) (Turesky et al. 1970) and visual analogue scales (VASs) (Huskisson 1974) indicating dentine hypersensitivity levels responding to tactile and air stimuli were assessed. The GBI was recorded 10–30 s after running a periodontal probe (PCPUNC 15 Hu–Friedy, Chicago, IL, USA) along the gingival sulcus of all teeth present and at six locations around each tooth (mesio-buccal, mid-buccal, disto-buccal, mesio-lingual, mid-lingual and disto-lingual). The PI was measured on the buccal and lingual surfaces of the teeth using the Turesky et al. (1970) modification of the Quigley & Hein (1962) plaque index. Dentine hypersensitivity to tactile stimulus was determined using a dental explorer (EXD 11-12 Hu–Friedy) drawn across the cervical area of each tooth at an approximated constant force. Approximately 10 min after the tactile stimulation, the hypersensitivity response to air blast was evaluated using a 1 s application of air from a standard dental unit syringe of 40–65 psi at a temperature of 17–21°C. The air blast was directed perpendicularly to the exposed dentine at a distance of 1–3 mm after isolating the test tooth.

The subjects were asked to record their perceived sensitivity during the application of stimuli on a 10 cm VAS, anchored at each end by the phrases ''No Pain'' and ''Unbearable Pain''.

The subjects were then randomly allocated to one of the three study groups. They were given the assigned toothpaste and a soft-filamented toothbrush for a 12-week period of home use. The identities of toothpaste were concealed. In addition, the participants were instructed to cover the entire length of the filament section of the toothbrush with the toothpaste and to brush their teeth twice daily, in the morning and in the evening, for 2 min each time. The use of any oral hygiene products other than those assigned for the study was not permitted. No interdental cleaning was advocated. At 4 and 12 weeks after the baseline examination, the participants were re-examined for GBI, PI and VASs for dentine hypersensitivity to tactile and air stimuli. Only the tooth showing the highest VAS at the baseline was selected for the VAS reassessments at weeks 4 and 12. In an attempt to monitor compliance, return of toothbrushes and unused toothpaste was requested and the toothpaste preparations were resupplied every 4 weeks. All measurements in this study were performed by a single investigator (D. K.). To ensure the reliability of this investigator, approximately 10% of the GBI and PI measurements were conducted twice at random. Spearman's correlation coefficients were calculated between the first and second measurements for each score separately. Correlations were strong, 0.96 for both GBI and PI scores, demonstrating excellent intra-examiner reliability.

Statistical analysis

Data analysis was performed using SPSS/PC+ version 9.0. Means and 95% confidence intervals (CI) were calculated for GBI and PI. The effects of toothpaste type over time were assessed by two-way repeated-measures ANOVA, with post hoc least significant difference (LSD) comparison. The two-tailed p-value of 0.05 was chosen to detect significant results.

Results

The mean age (standard deviation) of the participants was 35.7 (7.9) years, and the majority (78.4%) was female. The characteristics of the three comparison groups were similar with regard to age, gender and number of teeth (Table 1).

GBI and PI scores

Baseline GBI and PI scores did not differ by group and are reported in Table 2. The GBI score was reduced significantly after baseline in all groups ($p < 0.01$). Post hoc comparison demonstrated that the significant difference from baseline was seen at week 12 ($p < 0.05$). However, there was no significant difference in GBI score among the three comparison groups ($p = 0.46$).

For PI score, there was a significant interaction effect among the comparison groups over time ($p = 0.01$). Although there was no significant difference among the three groups, the PI score decreased in the test group and benchmark group from baseline to the end of study, but no significant changes were observed in the control group. Post hoc comparison indicated that test group was associated with a significant decrease from baseline in PI score at week 4 ($p = 0.02$), whereas the control and benchmark groups were not associated with any decrease in PI score over the same period.

VAS response for tactile and air stimuli

The three comparison groups had similar mean VAS sensitivity scores for tactile stimulus at baseline (Fig. 1). There was an overall significant change in the mean scores over time ($p = 0.01$). In the test group, the mean score (95% CI) decreased from 5.32 (4.72–5.92) cm at baseline to 3.17 (2.31–4.04) cm at week 4, and 2.30 (1.61–3.00) cm at week 12. The reduction pattern was similar in the control group with a score of 5.86 (5.21–6.52) cm at baseline, 3.42 (2.50–4.35) cm at week 4 and 1.79 (0.99–2.60) cm at week 12. The changes in the benchmark group were comparatively small, from 5.92 (5.34–6.50) cm at baseline to 4.67 (3.79–5.56) cm at week 4 and 3.83 (3.02–4.64) cm at the end of the study. The difference among the three groups was significant ($p = 0.01$). Post hoc comparison showed that the reduction in score was greater in both the test group and the control group as compared with the benchmark

Table 1. Characteristics of the subjects

Characteristic	Comparison group* test group ($n = 34$)	control group ($n = 34$)	benchmark group ($n = 34$)
age (years) (mean ± SD)	35.7 ± 7.3	36.4 ± 8.1	34.9 ± 8.6
female *n* (%)	27 (79.4)	26 (76.5)	27 (79.4)
number of teeth (mean ± SD)	26.9 ± 1.6	26.9 ± 1.4	27.3 ± 1.1

*Test group: toothpaste containing 5% potassium nitrate, 0.3% triclosan and 0.76% sodium monofluorophosphate (SMFP); Control group: toothpaste containing 5% potassium nitrate and 0.76% SMFP; Benchmark group: toothpaste containing only 0.76% SMFP.

Table 2. Gingival bleeding index (GBI) and plaque index (PI) scores at baseline, week 4 and week 12 among three comparison groups

Outcome measure	Comparison group* test group ($n = 34$)	control group ($n = 34$)	benchmark group ($n = 34$)
GBI, mean (95% confidence interval)			
baseline	30.08 (26.99–33.17)	29.90 (27.56–32.24)	31.33 (27.74–34.91)
week 4	27.81 (25.24–30.39)	28.88 (25.81–31.95)	31.40 (28.19–34.61)
week 12	26.45 (23.51–29.38)	28.23 (25.18–31.28)	28.49 (25.38–31.60)
PI, mean (95% confidence interval)			
baseline	1.93 (1.75–2.11)	1.90 (1.75–2.05)	1.89 (1.75–2.03)
week 4	1.80 (1.66–1.93)	1.87 (1.72–2.02)	1.90 (1.76–2.04)
week 12	1.80 (1.68–1.92)	1.90 (1.76–2.04)	1.75 (1.61–1.88)

*Test group: toothpaste containing 5% potassium nitrate, 0.3% triclosan and 0.76% sodium monofluorophosphate (SMFP); Control group: toothpaste containing 5% potassium nitrate and 0.76% SMFP; Benchmark group: toothpaste containing only 0.76% SMFP.

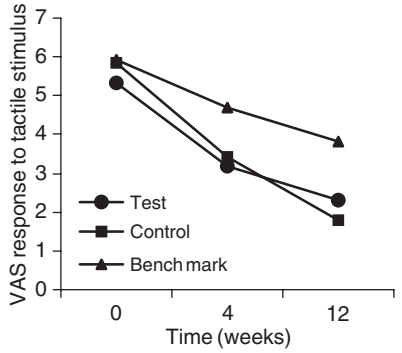

Fig. 1. The visual analogue scale (VAS) for sensitivity to tactile stimulus at baseline, week 4 and week 12 among three comparison groups: test group ($n = 34$): toothpaste containing 5% potassium nitrate, 0.3% triclosan and 0.76% sodium monofluorophosphate (SMFP); control group ($n = 34$): toothpaste containing 5% potassium nitrate and 0.76% SMFP; benchmark group ($n = 34$): toothpaste containing only 0.76% SMFP.

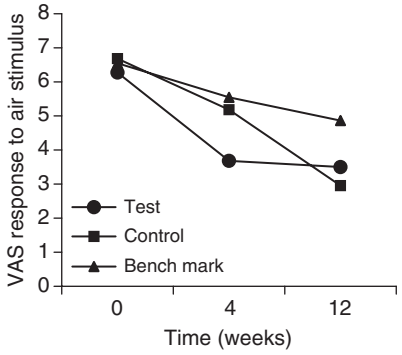

Fig. 2. The visual analogue scale (VAS) for sensitivity to air stimulus at baseline, week 4 and week 12 among three comparison groups: test group ($n = 34$): toothpaste containing 5% potassium nitrate, 0.3% triclosan and 0.76% sodium monofluorophosphate (SMFP); control group ($n = 34$): toothpaste containing 5% potassium nitrate and 0.76% SMFP; benchmark group ($n = 34$): toothpaste containing only 0.76% SMFP.

group ($p < 0.05$). However, there was no difference in the mean scores between the test group and the control group at any time point.

Fig. 2 illustrates the changes in mean VAS sensitivity scores for air stimulus in response to toothpaste use. The scores were similar among the three comparison groups at baseline. The score decreased most rapidly in the test group, from 6.26 (5.61–6.91) cm at baseline to 3.69 (2.76–4.62) cm at week 4, then leveled off at week 12 (3.49, 2.63–4.34 cm). In contrast, the score in the control group decreased slightly from 6.68 (6.00–7.35) cm at baseline to 5.20 (4.17–6.24) cm at week 4, then significantly leveled down to 2.97 (1.99–3.95) cm at week 12. However, there was no overall difference between the test group and the control group. There was only a slight change in VAS score in the benchmark group, with a score of 6.53 (6.09–6.98) cm at baseline, 5.56 (4.86–6.25) cm at week 4 and 4.87 (4.38–5.35) cm at study end.

Discussion

The present study investigated the effect of a new toothpaste containing 5% potassium nitrate, 0.3% triclosan and 0.76% SMFP on gingival health, plaque formation and dentine hypersensitivity. A number of studies have demonstrated that triclosan possesses antiinflammatory and antiplaque effects (Saxton et al. 1987, Svatun et al. 1987, 1989, Clerehugh et al. 1989, Garcia-Godoy et al. 1990, Lindhe et al. 1993, Palomo et al. 1994, Gaffar et al. 1995). In this study, there was no significant difference in the decrease in GBI and PI scores among the three comparison groups.

There are several factors in toothbrushing studies that might obscure the beneficial activity of the antiplaque and antigingivitis chemical products. One is the so-called Hawthorne effect (Owens et al. 1997). The repeated encounters with dental health personnel, repeated oral examinations, and the free supply of dentifrice and toothbrush in the present study might have motivated the subjects to improve their oral hygiene irrespective of the toothpaste type they received. In this study, toothbrushing was selected for oral hygiene care based on the fact that it is the actual method used to apply dentifrice. A number of studies using toothbrushing method found that the effects of triclosan in dentifrice on gingival inflammation and plaque formation was not clearly evident (Binney et al. 1996, Owens et al. 1997). This is not surprising because the reduction of GBI and PI scores by the mechanical method (brushing) alone is much greater than that by the chemical agents. When combined with the mechanical plaque control method, the antigingivitis and antiplaque activity of triclosan contained in the test toothpaste may not be large enough to demonstrate a significantly additive impact. In contrast, in studies where subjects did not brush and were asked to rinse with the dentifrice containing triclosan in water slurries or to apply the dentifrice containing triclosan via a soft acrylic toothshield, significant reductions in plaque and gingival inflammation were demonstrated (Saxton 1986, Saxton et al. 1988, Jones et al. 1990, Binney et al. 1997, Nogueira-Filho et al. 2000).

The antiplaque and antigingivitis activity of toothpaste containing triclosan may be enhanced by the presence of zinc citrate or polyvinylmethyl ether maleic acid copolymer in the toothpaste (Gaffar et al. 1990, Volpe et al. 1996, Gaffar et al. 1997). It was shown in clinical studies that toothpaste containing triclosan in the presence of either zinc citrate or copolymer possessed greater antiplaque and antiinflammatory effect when compared with the efficacy of toothpaste containing triclosan alone or placebo (Saxton 1986, Saxton et al. 1988, Garcia-Godoy et al. 1990, Palomo et al. 1994). The test triclosan toothpaste in this study did not contain zinc citrate or the copolymer. Therefore, it is possible that the antiplaque and antigingivitis activity of the triclosan in this newly formulated toothpaste is not optimized.

Several clinical studies have demonstrated that the dentifrice containing potassium nitrate provides effective desensitization (Tarbet et al. 1980, 1982, Silverman 1985, Nagata et al. 1994, Silverman et al. 1996, Sowinski et al. 2001). The mechanism by which potassium nitrate reduces dentine hypersensitivity may involve the depolarizing action of the K^+ ion resulting in the decrease of dentinal sensory nerve activity (Markowitz et al. 1991, Peacock & Orchardson 1995). Consistent with other previously reported clinical studies, we found that both test and control toothpaste types containing 5% potassium nitrate with and without 0.3% triclosan, respectively, were able to effectively reduce dentine hypersensitivity. This was shown by the overall significant reduction in the mean VAS sensitivity scores for tactile (Fig. 1) and air stimuli (Fig. 2) after the use of test and control toothpastes when compared with the use of benchmark product. This implies that triclosan does not have an inhibitory effect on the desensitizing activity of potassium nitrate in the toothpaste. Interestingly, at week 4, the VAS sensitivity score in response to air stimulus decreased the most in the test group, whereas the scores in the control

and benchmark groups decreased slightly (Fig. 2).

In conclusion, our present study has studied the efficacy of a new toothpaste containing the antiplaque and anti-inflammatory agent (0.3% triclosan), desensitizing agent (5% potassium nitrate), and anticaries agent (0.76% SMFP). It was found that the toothpaste was effective in reducing dentine hypersensitivity. More studies are needed to further determine the potential interaction between triclosan and potassium nitrate in the dentifrice.

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